Report of the
Health Economics Resource Center
to the VA Cooperative Studies Program

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Executive Summary

The Health Economics Resource Center (HERC) is the economics coordinating center for CSP. HERC is involved in planning, implementation, and analysis of clinical trials coordinated by all five CSP statistical coordinating centers. It provides the primary economist to trials coordinated by the Boston, Palo Alto, and West Haven centers. HERC is also making improvements to the VA economics infrastructure needed by CSP. HERC economists consult with CSP investigators and economists, the VA research service, and VA managers and clinicians. HERC receives additional core funding from the VA Health Services Research & Development Service and project-specific funding from VA and NIH.

Study planning. HERC coordinates the review of new CSP planning letters to evaluate the need for an economic analysis. *Four* planning letters were reviewed in the past year and economic analysis was recommended for *two* of these studies, and the decision on the inclusion of economic analysis for *one* study was been deferred until after the first planning meeting. HERC developed criteria for inclusion of cost-effectiveness in CSP trials. It is based on a systematic review CSP studies conducted by HERC and other CSP economists. In the past year HERC economists helped plan *five* studies**,** *two* of which were reviewed. A study on the treatment of schizophrenia (CSP 555) was approved for full funding and a study of self management for COPD (CSP 560) was approved for a pilot study; both are now in the start-up phase. *Two* other studies will be reviewed in the fall and a third is just starting the planning process. *Four* studies from the previous year have advanced from the planning process to the project start-up phase; evaluation of an innovative but expensive treatment for rheumatoid arthritis (CSP 551), evaluation of a long-acting antipsychotic drug for treatment of schizophrenia (CSP 555), evaluation of robot-assisted rehabilitation of patients who have a stroke (CSP 558), and evaluation of a program to prevent the acute exacerbations of Chronic Obstructive Pulmonary Disease (CSP 560).

Ongoing studies. HERC economists worked on seven CSP studies that are actively recruiting and following patients. These include studies of treatment strategies for HIV (CSP 512) and heart disease (CSP 424), a comparison of radial artery to saphenous vein grafts in heart bypass surgery (CSP 474), a study of intensive renal support for acute renal failure (CSP 530), evaluation of home monitoring of anticoagulation therapy (CSP 481), and integrating smoking cessation into the mental health care of Post Traumatic Stress Disorder (PTSD) patients (CSP 519). In the past year, patient enrollment began in a study that examines adjuvant therapy for prostate cancer (CSP 553). A project analyzing methods of collecting patient utilities (CSP 146) is nearly complete.

Recent significant economic findings of CSP studies. In the past year, HERC economists conducted continuing analyses on *three* studies. A *fourth* study entered the primary analysis phase. Results from the economic components of these studies yielded the following notable findings:

Geriatric Evaluation and Management (GEM) units were not less expensive than usual care. However, GEM patients had significantly fewer nursing home admissions The paper reporting these results was published in Medical Care (CSP 006).

Relatively small differences in symptom levels in Post Traumatic Stress Disorder (PTSD) were associated with notable differences in labor market outcomes. This implies that even partial improvements in PTSD symptom levels may help patients achieve more employment and more income (CSP 420). This finding was published in Mental Health Services Research.

Percutaneous coronary intervention was found to be less costly and more effective than coronary artery bypass graft for the urgent revascularization of medically refractory, high-risk patients. This finding is in press in Circulation (CSP 385).

Positron emission tomography was found to be a cost-effective in the diagnosis of solitary pulmonary nodules if it is used selectively, when pre-test probability of lung cancer and computed tomography findings disagree, or in patients with intermediate pre-test probability who are at high risk for surgical complications. This finding was published in the Annals of Internal Medicine. Meta-analyses of PET test

characteristics were published in JAMA and the Annals of Internal Medicine. The results of a survey of study sites on the cost of PET were published in the American Journal of Roentgenology. CSP approved a supplemental study to combine study results with administrative data. An analysis of health care utilization, cost, and outcomes of sub-groups of patients with solitary pulmonary modules is now underway (CSP 027).

Methods papers for two current studies were published in the Journal of Thrombosis and Thrombolysis (CSP 481) and in Clinical Trials (CSP 530) and a third is in press in the American Heart Journal (CSP 424).

Coordination of economic analysis for CSP. HERC convenes quarterly conference calls of CSP economists. This forum allows CSP economists to reach consensus, providing the program with a consistent approach to economic evaluation. HERC is completing guidelines for assessing utilities, the health outcome measures used in cost-effectiveness analysis. These guidelines are being developed for an audience of CSP economists, biostatisticians, and planning committees.

CSP leadership. A HERC health economist chaired the CSP committee that recommended ways for Clinical Sciences Research and Development Service to monitor clinical practices with electronic databases. HERC also helped develop draft performance criteria for CSP centers.

Assistance to VA Headquarters. Mark Smith was detailed to ORD part-time to assist the Deputy CRADO with several projects. Paul Barnett and Todd Wagner are assisting CRADO with an evaluation of the economic impact of VA research. Ciaran Phibbs conducted an analysis of the cost of expanding the VA benefit package to cover the infant for VA covered deliveries for the Director of the Women's Veterans Health Program. Mark Smith designed an analysis plan to study the relation between PTSD benefits and return-to-work behavior among Vietnam-era veterans for the Director of the HSR&D Management Consultation Service. Ciaran Phibbs helped VISN Service Support Center staff develop methods to estimate the potential non-VA costs of services currently provided by VA to support management make-or-buy decisions.

Development of VA economics infrastructure. HERC updated its average cost data set, the comprehensive estimates of the cost of all VA health care encounters. HERC also evaluated national data extracts from the Decision Support System, the VA cost allocation system. HERC economists documented methods of estimating the cost of physician services, VA labor costs, and pharmacy costs. HERC conducts a health economics course for VA investigators, and coordinates a monthly VA health economics seminar. The course and monthly presentations use a distance learning technology, a web broadcast and simultaneous telephone conference. HERC taught health economics at the 2006 Seattle ERIC summer course.

Service work. HERC economists serve on VA advisory and steering committees and conduct biostatistical reviews of Merit Review proposals. They provide consultative advice to VA managers and conduct research on important managerial questions. They participate in scientific review for a number of journals, the VA Clinical, Laboratory, and Health Services Research Services, the National Institutes of Health, the Centers for Disease Control, and several foundations.

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SECTION I. – UPDATE OF STUDIES

PROJECTS IN PLANNING STAGE

CSP STUDY 562 - A Randomized Trial of Actinic Keratosis Treatment Modalities for the Prevention of Basal and Squamous Cell Carcinoma of the Skin (The VA AK Trial)

Study Economist: Ciaran S. Phibbs, Ph.D.
HERC

BACKGROUND/RATIONALE

Keratinocyte Carcinoma (KC), of which Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC) are the predominate types, are very common skin cancers, both in VA, and in society as a whole. In FY 2005 VA treated over 130,000 veterans for KC and over 230,000 veterans for its precursor, actinic keratosis (AK). Sun exposure is a major risk factor for KC and AK, which puts many veterans at increased risk due to service in areas with high sun exposure. 5-fluorouracil (5-FU) is a topical cream that is an FDA approved therapy for AK and early stage BCC. There is evidence that preventive therapy with 5-FU will treat KCs that are not yet clinically apparent.

OBJECTIVE

To see if preventive treatment with 5-FU for patients at high-risk for KC reduces the incidence of KC over the following 2 to 4 years. The study will measure both time to first BCC and first SCC. Secondary objectives include the prevention of AK, overall cost-effectiveness, quality of life, and the frequency and severity of specific anticipated side effects of treatment.

RESEARCH PLAN

This study will recruit 1500 patients over two years at 15 VA medical centers. The study will recruit patients at high-risk for KC based on having been treated for two or more KCs in the prior five years, with at least one of these KCs having occurred on the face or ears. Half (750) of the subjects will be randomly assigned the intervention of twice daily treatment with 5-FU for four weeks, for a total of 56 treatments. Patients who have problems tolerating the treatment will reduce the frequency of treatment and continue until all doses have been administered. Control patients will receive a placebo cream. Patients will be recruited over two years, with a minimum follow-up period of two years, with all patients followed until the end of the study. DSS data will be used to capture VA costs and patient self-report will be used to capture non-VA utilization. The disease-specific measure (Skindex) will be used to measure quality of life. General health utilities measures are not included, as previous work has shown than they do not detect differences for this condition. If needed, Skindex will be used to identify the relevant health states and community rated utilities will be obtained for these health states. But, if the intervention works as expected it will not be necessary to obtain utilities as initial calculations indicate that strong dominance is the likely outcome of the trial.

IMPACT STATEMENT

KCs are very common and it is thought that their incidence will increase markedly in the coming years as the population ages. If chemo-preventive therapy with 5-FU works as expected, the potential impact is very large, both for VA and the entire country. Preliminary calculations indicate that this is one of those rare interventions that will both improve outcomes and reduce total health care costs.

DURATION OF STUDY
Two years of recruitment, with a minimum of two years of follow-up.

FUNDING
Unknown

CSP STUDY 565 - Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy

Study Economist: Patricia Sinnott, PT, PhD, MPH
HERC

BACKGROUND / RATIONALE

Diabetes is the leading cause of end-stage renal disease (ESRD) in the United States and medications that block the renin angiotensin system have been shown to decrease the progression of diabetic nephropathy by better controlling high blood pressure. The standard treatment for treatment of this high blood pressure associated with diabetes is an angiotensin converting enzyme inhibitor (ACEI) or an angiotensin receptor blocker (ARB). There are no data on outcomes for the use of combination ACEI/ARB therapy in patients with diabetes, however, the combination of an ACEI and ARB has been shown to decrease the risk of disease progression in one study of non-diabetic kidney disease, and shown to decrease proteinuria in short-term studies in diabetic kidney disease. Though there are encouraging results for change in proteinuria results, there could be an increased risk of hyperkalemia in individuals with diabetes, treated with the combination therapy.

OBJECTIVES AND METHODS

This proposed study, CSP 565, is a randomized double blind multi-center clinical trial to assess the effect of combination ACEI and ARB in patients with diabetes and proteinuria on progression of renal failure. The second primary objective is to assess the safety of the intervention. It will be a multisite, randomized, controlled clinical trial. It will enroll 2096 veterans with type 2 diabetes and albuminuria > 300mg/gram creatinine. Veterans will be excluded if they have a history of intolerance to ACEI or ARB, current use of ACEI/ARB combination, history of non-diabetic kidney disease, potassium level > 5.5 meq/L or currently taking sodium polystyrene, uncontrolled diabetes, pregnancy or an estimated glomerular filtration rate < 30 ml/min/1.73m^2. Patients will all receive an open label ARB, which is standard of care in VA. They will be converted to losartan (an ARB) and the dose titrated to 100mg/day. Individuals who continue to meet the eligibility criteria will be randomized in a 1:1 ratio to the addition of blinded lisinopril (the ACEI) or placebo. The medication (lisinopril or placebo) will be titrated from 10mg to 40mg/day. After each adjustment in dose, blood work will be checked for kidney function and potassium levels. Individuals will be seen every three months after titration. They will continue in the study for up to five years.

The primary efficacy endpoint is doubling of serum creatinine or progression to end-stage renal disease. Secondary endpoints are quality of life (as measured by the Health Utilities Index) and hospital admission for heart failure. Tertiary outcomes are change in albuminuria at 6 and 12 months, decline in slope of kidney function, and cardiovascular events (myocardial infarction, cerebrovascular accident, cardiac or peripheral revascularization, or lower extremity amputation). The primary safety endpoint is all-cause mortality and the secondary safety endpoint is occurrence of serious hyperkalemia (K>6 meq/L or requiring admission, emergency room visit or dialysis).

A limited economic analysis has been proposed for CSP 565. The intervention (combination therapy) is very likely to be cost-saving relative to usual care (monotherapy). A review of prior studies revealed that ACEI and ARB treatments that control blood pressure are in most cases cost-saving [1, 2] and treatments that delay the development of ESRD are cost-effective relative to no treatment, by conventional standards [3, 4]. In the proposed study, combination therapy is expected to increase the five-year cost of care by less than $500 per patient above standard care. Smith and Richardson [5] estimated that the range of hemodialysis treatment cost for a single VA patient was $55,224 to 84,864/year in FY2003, assuming a usual treatment schedule of dialysis three times a week. If even one patient in 100 receiving combination therapy experiences a delay in ESRD onset of a single year, then the combination therapy will produce cost-savings. We estimate that the effect of the combination therapy in fact will be substantially greater. In addition, patients on dialysis report quality of life 25-50% below those on medication alone. Thus, any delay in progression to ESRD and/or dialysis would be expected to improve patient quality of life. [1, 2, 6-

8]

In this case, because the cost of the intervention is so low when compared to the potential long-term cost savings and quality of life benefit, a standard cost-effectiveness analysis has not been planned. However, if, after four years, the combination therapy intervention proves effective, we have proposed to do a business case analysis to inform VA managers of the year-by-year costs and savings from combination therapy. Data for this analysis will be collected during the study. Non-VA utilization data will be collected by patient self-report. We will assign such stays the average cost of similar VA stays.

Two planning meetings have been held. The study will be reviewed by CSSMRB in November 2006.

IMPACT STATEMENT

The study proponents postulate that combination ACEI/ARB therapy will result in a 22.5% relative reduction in progression of kidney disease from an absolute level of 30% to 23.3%. This relative reduction in progression in kidney disease is estimated to produce a significant reduction in the demand for kidney dialysis, with associated improvement in quality of life for these veterans. Additionally, this reduction in demand is estimated to produce a cost savings of approximately $88,800,912 - $136,461,312 over five years[i].

DURATION OF STUDY
Four years

FUNDING
In planning; possibly a national study additionally supported by NIDDK.

[i] Proponents estimate 24,000 veterans in stage IV of chronic kidney disease and 30% converting to end stage renal disease. Proponents estimate 22.5% decrease in conversion to 23.3%. Range of savings estimated ((6.7%*24000)*$55,224) – ((6.7% *24000)*84864).

CSP STUDY 568 - Improving the Quality of Life for Patients with Malignant Bowel Obstruction

Study Economist: Paul G. Barnett, Ph.D.
HERC

BACKGROUND / RATIONALE

Malignant Bowel Obstruction occurs in 10% to 28% of colorectal cancer patients and results in substantial patient suffering and survival of less than 3 months. There is little evidence on the most appropriate palliative care for patients with this condition. Surgery can improve quality of life in 42% to 85% of patients, but operative mortality is high, and re-obstruction after surgery is high.

OBJECTIVES

This trial will compare surgical and medical management of malignant bowel obstruction to identify patients' sub-groups who can benefit from each approach, and to determine the effect of each method on patient quality of life and health care cost. The economic evaluation would determine if the expense of surgery is justified by the gain in quality adjusted life years.

RESEARCH PLAN

Patients with malignant bowel obstruction who are candidates for surgical intervention will be randomized between surgery and a strategy of initial medical management, including antiemetics, corticosteriods, opioids, and ocreotide, a synthetic analog of a gut hormone. Patients who do not improve with medical management will be offered surgery. The study will examine cost and patient quality of life.

STATUS

First planning meeting was held in June 2006.

IMPACT STATEMENT

There were 52,672 new cases of colorectal cancer cases in VA during the last 5 years. Malignant bowel obstruction occurs in 10% to 28% of colorectal cancer cases. Other cancers, including ovarian cancer, can also result in bowel obstruction. Most malignant bowel obstruction results in a hospital stay, but there is no evidence whether surgery or medical treatment is the appropriate approach.

DURATION OF STUDY

The letter of intent anticipates a study of 2-3 years' duration.

PROJECTS APPROVED – AWAITING START-UP

CSP STUDY 558 - Robotic Assisted Upper-limb Neurorehabilitation in Stroke Patients

Study Economist: Todd H. Wagner, Ph.D.
HERC

BACKGROUND / RATIONALE

Recent advances in clinical neuroscience research and robotic bioengineering have now made it possible to consider using novel robot devices to provide task-specific neurorehabilitation for the recovery of neurological function in persons with neurological injury. A small number of studies have suggested that robotic-assisted neurorehabilitation training for the upper extremity is clinically effective for improving motor outcomes of the shoulder and elbow in stroke patients. Confirmation of these results in a larger multi-site trial is warranted. This is a three-arm trial comparing the safety and efficacy of robotic assisted rehabilitation to high-intensity usual care and usual care.

OBJECTIVE

The primary endpoint of the study is the Fugl-Meyer scale. The proposed economic analysis will evaluate the incremental costs per quality adjusted life year. The CEA is based on a conditional design and will only be conducted if the robot is superior to usual care on the Fugl-Meyer scale.

RESEARCH PLAN

We propose a 36-week, randomized, trial comparing robotic assisted rehabilitation, intensive conventional therapy and usual care in patients with a stroke-related upper extremity injury. The target sample is 158 patients, and this will provide 90% power to detect a 5% mean difference in the Fugl-Meyer scale between robot training and usual care. There will be one interim analysis of the primary endpoint at 12 months for the purpose of sample size re-estimation.

The economic analysis will be conducting using the societal perspective. Health care utilization and cost data from both VA and non-VA facilities will be collected. The VA data will be collected from the VA cost database and non-VA data will be collected through self-report. Quality of life will be measured by two instruments: Health Utilities Index Mark 3 (HUI3) and a Visual Analog Scale (VAS).

IMPACT STATEMENT

This study may impact methods for rehabilitating stroke patients with upper extremity injuries.

DURATION OF STUDY

Awaiting Kickoff

FUNDED - IN START-UP

CSP STUDY 551- Rheumatoid Arthritis: Comparison of Active Therapies in Patients With Active Disease Despite Methotrexate Therapy

Study Economist: Ciaran S. Phibbs, Ph.D.
HERC

BACKGROUND / RATIONALE

Methotrexate is the standard first-line therapy for rheumatoid arthritis. For patients who do not respond to methotrexate therapy, the standard of care is multiple drug therapy. Anti-tumor necrosis factor alpha (TNF) therapy is a promising, but more expensive, new biological therapy for treatment of rheumatoid arthritis (about $10,000/year compared to about $1,000/year for standard care). Both alternative therapies have been shown to be effective for patients who do not respond to methotrexate, but they have not been directly compared with each other. This study will compare the effectiveness and cost-effectiveness of alternative therapies for patients who do not respond to methotrexate therapy.

OBJECTIVES

This study will compare standard therapy (methotrexate plus sulfasalazine plus hydroxychloroquine) with TNF therapy for the treatment of patients with rheumatoid arthritis who have failed to respond the treatment with methotrexate alone. The primary endpoint will be clinical improvement, as measured by the Disease Activity Score (DAS-28), with cost-effectiveness as a secondary endpoint.

RESEARCH PLAN

This study is funded with a kick-off meeting tentatively scheduled for October or November 2005. The initial design is a randomized, double blind trial, with a one year follow-up period. The economic evaluation will assess costs and quality of life. Quality of life will be measured using the Health Utilities Index (HUI) and a single visual analog scale question. The cost-effectiveness analysis will be based on a model of the patient's lifetime to provide a complete economics evaluation. Data from the study will provide information for the one year study period. Data beyond one year will come from literature reviews. The study will be designed from the societal perspective. Health care utilization and cost data from both VA and non-VA facilities will be collected. The VA data will be collected from the VA cost databases. Non-VA data will be collected through a trial report form. To facilitate the adoption of the study results by VA managers, a second economic analysis will be done from the perspective of VA managers. This will be a cost-consequences analysis, not a cost-effectiveness analysis, and the main focus will be a one year time horizon.

IMPACT STATEMENT

Rheumatoid arthritis is a condition that is becoming increasingly important at the VA population ages. There is a large cost difference between the two therapies

DURATION OF STUDY
In start up, tentative duration 1/07-7/09

FUNDING
$10,929,326

CSP STUDY 555 - Impact of Long-Acting Injectible Risperidone on Cost Effectiveness of Treatment for Veterans with Schizophrenia

Study Economist: Paul G. Barnett, Ph.D.
HERC

BACKGROUND / RATIONALE

Anti-psychotic medications have improved the treatment of schizophrenia, allowing millions of people to live outside of institutions. Medication non-adherence is recognized as perhaps the most important determinant of relapse. It results in both hospitalization and self-injurious behavior. Because it has a lower risk of extrapyramidal symptoms, long-acting IM risperidone holds substantial promise for improving the acceptability, and as a result, the net effectiveness of anti-psychotic pharmacotherapy. Cost-effectiveness concerns may govern adoption of this therapy, as long-acting IM risperidone is expensive, costing $5,000/patient/year.

OBJECTIVES

The study will evaluate the impact of long-acting IM risperidone on the risk of inpatient psychiatric hospitalization in comparison to standard oral anti-psychotic treatment in a randomized controlled trial of 600 veterans diagnosed with schizophrenia or schizoaffective disorder over three years. It will also evaluate the incremental cost-effectiveness of this pharmacotherapy.

RESEARCH PLAN

600 veterans at 17 VA medical centers who have a primary diagnosis of schizophrenia or schizoaffective disorder and at least one psychiatric hospitalization in the previous year will be randomly assigned to either long-acting injectable risperidone or doctor's choice of oral antipsychotic medication. Data on cost, utilization, and re-hospitalization will come from VA medical records and national administrative data. Assessments at baseline and every 6 months until the end of follow-up will be done using the PANSS, the Heinrichs Carpenter Quality of Life Scale, and the Quality of Well Being Scale. We will determine the cost of study medication and screening patients. DSS data will be used for other health care cost. Patient incurred costs will be determined. The incremental cost-effectiveness ratio will be found to determine if the benefit of the intervention justifies its cost.

STATUS

Study kick-off meeting was held in June, 2006.

IMPACT STATEMENT

Schizophrenia is the most disabling psychiatric disorder. Among 100,000 VA patients with schizophrenia, about 18% are hospitalized each year for this disease. This study is focused on this high-cost, high-risk population. VA physicians rapidly shifted from older oral medications to second-generation anti-psychotics. If there is a similarly rapid adoption of long-acting IM risperidone, VA could incur an additional $50 million in annual drug costs. Such adoption may occur even in the absence of data on the effectiveness or cost-effectiveness sought by this trial.

FINDINGS

DURATION OF STUDY
The trial is planned to include two years enrollment, an additional year for follow-up, and one-year to complete analyses.

FUNDING

CSP is providing funding for 5% FTE for HERC health economist Paul Barnett to participate in this study.

CSP STUDY 560 - Bronchitis and Emphysema Advice and Training to Reduce Hospitalization (BREATH): A randomized controlled trial of strategies to prevent COPD hospitalizations

Study Economist: Todd Wagner, PhD
HERC

BACKGROUND / RATIONALE

COPD is a condition characterized by airflow obstruction and lung hyperinflation that is largely irreversible. It has long been recognized that cigarette smoking plays an overwhelming role in the causation of COPD in industrialized nations, and that prevalence of the disease within such populations closely mirrors smoking habits with a delay of about 30 years. COPD imposes an enormous burden on the health care system. In the United States it is responsible for 14.2 million office visits, 1.4 million emergency department visits, and over 600,000 hospitalizations annually. Medicare beneficiaries with COPD have *per capita* medical expenditures that are nearly 2.5 times higher than those patients without COPD. Among patients 55 years of age and older, COPD is primarily or secondarily responsible for 18% of all hospitalizations, making it one of the leading causes of hospital care in the US. The overall direct and indirect medical costs of COPD for the United States in 2000 was estimated to be in excess of $ 30 billion annually.

The Veterans Affairs Medical System cares for a large number of patients with COPD, and the costs for this care are correspondingly large. The prevalence of COPD among patients in the VA general internal medicine clinics is as high as 22%. Exacerbations among patients with COPD frequently result in costly emergency room visits and hospitalizations. Within the VA system, there were 16,073 discharges for COPD in fiscal year 2003 associated with a mean length of hospital stay of 6.5 days.

OBJECTIVES AND METHODS

The objective of CSP 560 is to evaluate the efficacy and cost-effectiveness of a self-management intervention incorporating self-management education, an action plan, and case-management in reducing the number of COPD-related hospitalizations among veterans with severe COPD.

CSP 560 will be a multisite, randomized, controlled clinical trial. It will enroll 1,080 veterans with severe COPD who were hospitalized in the prior year. They will be randomized to one of 3 groups: 1) Comprehensive disease management program, 2) Targeted self-management education with action plan directed at early treatment of exacerbations, or 3) Usual care. Each of 18 VA study sites will enroll about 60 patients, or 20 patients for each study arm. Enrollment would be completed in 18-months, and the subjects followed for at least 12 months. The comprehensive group will receive an initial, intense education program and regular telephonic contacts by a case-manager. Patients in the targeted disease management arm will receive during a single site visit a 90-minute instructional video and careful instructions regarding action plan with two telephone refreshers about the action plan. Patients allocated to usual care will receive only an educational brochure about COPD. An independent assessor, blinded to intervention arm, will collect outcome information by telephone at two-month intervals. Other data will be derived from baseline study forms and administrative databases.

There will be several outcomes of interest. The primary objective is to compare the effect of a comprehensive disease-management program versus a targeted self-management action plan on the incidence of COPD hospitalization with usual care in a randomized controlled trial of 1,080 veterans diagnosed with severe COPD over two years. The secondary objectives include cost-effectiveness, adherence, and health benefits as measured by (a) VA and non-VA health services use and related costs, (b) health-related quality of life, (c) patient satisfaction with care, (d) medication adherence, and (e)

patients' knowledge, skill acquisition, and self-efficacy.

The economic analysis will consist of cost-effectiveness analyses from the perspective of VA and from the perspective of society. Data will be gathered from VA administrative databases, patient surveys, public mortality databases, and quality-of-life surveys. Data on non-VA inpatient stays will come from administrative records of those facilities, with patients' permission.

STATUS

A pilot study with six sites was approved by CSSMRB in November, 2005. Kickoff will occur in July, 2006. If the pilot study is successful, additional sites will be added.

IMPACT STATEMENT

COPD exacerbations are costly, with an estimated mean cost of $9,581 per hospitalization in the VA based on national DSS data. An economic analysis in a non-VA system found that hospitalizations contributes to more than 70% of the costs for caring for patients with COPD. Disease management might reduce COPD hospitalizations and may even save money relative to usual care.

DURATION OF STUDY
Pilot study: 07/06 – 06/07

FUNDING
$41,653

ONGOING PROJECTS – PATIENT ACCRUAL STAGE

CSP STUDY 146 - Preference Measurement for Trial-Based Economic Evaluations

Study Economist: Paul G. Barnett, PhD
HERC

BACKGROUND / RATIONALE

Preferences, also known as patient utilities, are a measure of the effect of health status on quality of life that are used to value the effect of health interventions in cost-effectiveness analysis. There are no standards for how patient utilities should be measured in VA Cooperative Trials; several different methods have been used. The choice of methods to measure patient utilities can potentially affect the results of cost-effectiveness analysis. This study is part of HERC's effort to coordinate a more systematic application of economic analyses to VA Cooperative Trials.

OBJECTIVES AND METHODS

The project will (1) conduct a literature review on preference measures and the alternatives, (2) survey CSP operational experience in preference measurement, (3) combine literature review and CSP experience into the development of practical guidelines for measuring quality of life outcomes, (4) develop a condensed review for non-economists, and (5) disseminate results via training provided to staff at CSP coordinating centers and students at the CSP investigators course.

STATUS

A manuscript, prepared by research psychologist Forest J. Baker, which describes the most often used methods of assessing utilities and criteria for assessing the merits of each method, is being revised and expanded by health economists Patsi Sinnott and Paul Bartlett. Seminars describing an overview of utility measurement methods have been provided in the HERC Health Economics Cyber Seminars in 2005 and 2006. These presentations are archived on the World Wide Web. Forest Baker's review of the literature on quality of life assessments in HIV/AIDS, which evaluates instrument responsiveness validity by assessing the correlations between instruments and subscales of the SF-36 and the HIV-MOS, is under review. Two seminars were presented to obtain feedback on these preliminary findings. This project provided recommendations for planning CSP 551, about the most appropriate way to measure HRQL utilities in patients with arthritis. Surveys of health economists and research coordinators involved in CSP health economics studies have been completed their operational experience in preference measurement will be summarized in the manuscript.

IMPACT STATEMENT

This special project will improve methods used by the Cooperative Studies Program to assess economic outcomes

DURATION OF STUDY
7/03-6/05

FUNDING
$112,288

PUBLICATIONS
Baker, FJ. A systematic review of the reliability, construct validity, and responsiveness of health-related quality of life measures within HIV populations. (Under review)

CSP STUDY 474 - Radial Artery vs. Saphenous Vein Grafts in Coronary Artery Bypass Surgery

Study Economist: Todd H. Wagner, Ph.D.
HERC

BACKGROUND / RATIONALE

The saphenous vein graft is a standard conduit for coronary artery bypass grafting to all areas of the heart except the left anterior descending (LAD) artery. Although the radial artery was introduced as a potential conduit for coronary artery bypass grafting in the 1970s, enthusiasm for its use was limited by the technical difficulty of harvesting the vessel and problems with perioperative vascular spasm. In spite of this, some surgeons persisted based on their belief that arterial conduits would be better than vein grafts, in terms of long-term patency. With the development of new harvesting techniques and the introduction of calcium channel blockers to prevent vasospasm, the use of the radial artery graft has increased in recent years. This use of the radial artery as a conduit is not based on any long-term prospective data regarding its patency. However, because the VA has been a leader in defining the long-term efficacy/patency of saphenous vein and internal mammary grafts, it is appropriate for the VA to investigate radial artery grafts. In fact, the VA under its Cooperative Studies Program, is probably the only health care delivery system that has the ability to undertake this study.

OBJECTIVE

Primary Hypothesis: radial artery grafts will have a higher graft patency rate at one year after coronary artery bypass graft surgery (CABG) compared to saphenous vein grafts. Secondary Hypotheses: to determine if there are any differences in clinical outcomes, cost and quality of life in patients receiving radial artery versus saphenous vein grafts.

RESEARCH PLAN

The study is a prospective, randomized, unblinded clinical trial. The population consists of VA patients with coronary artery disease documented by coronary arteriography who have agreed to undergo coronary artery bypass surgery. Medical conditions that could affect blood flow through the patient's arm are the main exclusion criteria. These include Raynaud's symptoms, a positive Allen test, neurologic or musculoskeletal disease affecting the arm, and patients with one arm. Patients who are eligible and agree to participate in the study will be randomly assigned to receive one radial artery graft or one saphenous vein graft to the following vessels: left anterior descending if internal mammary not used, circumflex, diagonal, and right coronary artery. The surgeon will determine the subject vessel preoperatively by selecting the vessel that is suitable for grafting. The stratification factors will be the participating hospital and the vessel to be bypassed, left anterior descending versus all other vessels. History, physical examination, laboratory tests, and cardiac catheterization will be performed at baseline and at one year. Follow-up clinic visits will be at two weeks, three, six, and nine months post CABG. Coronary angiography will be performed one week and one year post surgery. Quality of life and hand/leg functional status will be assessed at baseline, three months, and one year.

The economic analysis will be conducted using the societal perspective. Health care utilization and cost data from both VA and non-VA facilities will be collected. The VA data will be collected from the VA cost database and non-VA data will be collected through trial case report forms. The cost of the index admission will be calculated using data from the case report forms. Health care charges from non-VA facilities will be obtained from the hospital, with permission of the patient. Quality of life will be measured by the Health Utilities Index (HUI-3). The cost-effectiveness analysis will be based on the incremental cost per quality adjusted life year at one year post surgery.

For this trial, a sample size of 874 randomized patients will be required. This will provide 90% power to detect a difference in one year patency rates of 92% for the radial artery versus 83% for the saphenous vein and an expected one year catheter completion rate of 65%. This is a five-year study. There will be four years of patient accrual and one year of follow-up. Nine participating VA medical centers will be expected to randomize two patients per month.

IMPACT STATEMENT

This study may impact methods for conducting coronary artery bypass surgery.

DURATION OF STUDY
1/03-11/07

FUNDING
$6,000,000

CSP STUDY 519 - Integrating Clinical Practice Guidelines for Smoking Cessation into Mental Health Care for Veterans with Posttraumatic Stress Disorder

Study Economist: Mark W. Smith, Ph.D.
HERC

BACKGROUND / RATIONALE

Tobacco use is the single most preventable cause of morbidity and death in the United States. Nicotine dependence is a costly and potentially lethal disorder that strikes especially hard at veterans with chronic mental illness, including posttraumatic stress disorder (PTSD). Existing methods for delivering smoking cessation interventions often do not offer adequate access to treatment or address the special needs of a large population of nicotine-dependent veterans with PTSD.

OBJECTIVE

The objective of CSP 519 is to determine the most effective method for delivering evidence-based treatment for nicotine dependence to veterans undergoing care for PTSD in VA Specialized Outpatient PTSD Programs (SOPPs). The study will compare two alternative treatment methods, integrated care (IC) and usual standard of care (USC). IC is a guideline-based treatment for smoking cessation administered by the primary mental health care provider. Usual care consists of referral to a specialized smoking cessation clinic. It is hypothesized that smoking cessation interventions involving integrated care will be more effective than the usual standard of care, as measured by reduction in prevalence of tobacco use and other smoking-related clinical outcomes. The economic analysis will determine the cost-effectiveness of integrated care relative to usual care.

RESEARCH PLAN

CSP 519 is a multisite, randomized, controlled clinical trial. The protocol calls for a total of eight VA SOPPs to enroll 175 patients each over a period of 36 months. Due to slow enrollment, two additional sites will be added in late FY2006. Patients will be randomly assigned to the alternate treatments within sites, half into IC and half into USC. Data collection will consist of baseline demographic and clinical data. There will be follow-up data collected every three months through month 18, and every six months beyond that until the study end.

There are several outcomes of interest. The primary outcome is effectiveness, measured by prevalence of smoking abstinence in the 7 days prior to the post-randomization follow-ups. Salivary cotinine levels and CO readings verify smoking status. Secondary outcomes include rates of continuous abstinence from weeks 26-52 and other measures of smoking status, functional status and health-related quality of life, PTSD symptoms, depression symptoms, and cost-effectiveness.

The economic analysis consists a cost-effectiveness analysis from the perspective of VA and from the perspective of society. Data are being gathered from VA administrative databases, patient surveys, public mortality databases, and quality-of-life surveys (SF-36 and the Smoking Cessation Quality of Life instrument). The cost-effectiveness analysis will have a lifetime horizon because smoking cessation incurs costs at the outset but yields its full benefits only after many years. We will therefore model lifetime costs and outcomes (mortality, quality of life) using appropriate statistical methods.

IMPACT STATEMENT

Application of IC system-wide has the potential to generate far more non-smokers among PTSD patients than does usual care (USC), if the study hypothesis is confirmed. Nationwide, about 70% of smokers

want to quit, including 60% of mentally ill patients. We may assume conservatively that at least 50% of smokers with PTSD are receptive to treatment. IC treatment of all PTSD patients within VHA who are receptive to smoking cessation intervention would yield 12,000 additional quitters beyond the expected quite rates from USC, assuming successful outcomes of 20% and 10% for the two methods, respectively.

Stopping smoking is known to prevent a range of serious medical illnesses, prolong quality-adjusted life years, and significantly curtail health care costs. Both VA and veterans stand to gain from CSP 519.

DURATION OF STUDY
09/04 – 09/09

FUNDING
$11,000,000

PUBLICATIONS
McFall M, Saxon AJ, Thaneemit-Chen S, **Smith MW**, Joseph AM, Carmody TP, Beckham JC, Malte CA, Vertrees JE, Boardman KD Lavori PW. Integrating practice guidelines for smoking cessation into mental health care for post-traumatic stress disorder. Submitted for publication.

CSP STUDY 530 - Intensive vs. Conventional Renal Support in Acute Renal Failure

Study Economist: Mark W. Smith, Ph.D.
HERC

BACKGROUND / RATIONALE

Acute renal failure (ARF) is defined by the abrupt loss of renal function resulting in the failure of the kidney to excrete urea and other nitrogenous waste products. Despite more than a half-century of experience in the use of hemodialysis and other renal replacement therapies in the management of ARF, mortality remains high and many fundamental issues remain to be resolved. These include the indications for and timing of initiation of therapy, the optimal dose and modality of therapy, the selection of dialysis membranes, the composition of dialysate and replacement fluids, and indications for the discontinuation of therapy.

Intermittent hemodialysis is the most commonly prescribed form of renal support, usually provided on a 3-4 times per week schedule. Several recent clinical studies have suggested that more intensive renal support may result in improved survival. These studies have had significant limitations and have not been widely accepted in clinical practice.

OBJECTIVE

CSP 530 compares a strategy of intensive renal support to conventional management of renal replacement therapy in critically ill patients with acute renal failure. The primary clinical outcome is 60-day mortality from all causes. Secondary outcomes include all-cause in-hospital mortality, 12-month all-cause mortality, recovery of renal function, total costs after 60 days and after 12 months, and lifetime cost-effectiveness. The economic analysis tests whether intensive therapy is cost-effective relative to the control therapy. Analyses are being performed from societal and VA perspectives.

RESEARCH PLAN

CSP 530 is a multi-site, randomized, and controlled clinical trial. Since study inception, several sites have been replaced. The current roster includes 18 VA medical centers and 9 non-VA facilities whose participation is funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The study expects to enroll 1,400 patients over a 36-month period. Patients are be randomized to conventional therapy (three times per week) or intensive therapy (six times per week). Patients remain on the assigned regimen for up to 30 days. Clinical data are collected during the inpatient stay. Follow-up data are collected at 60 days and at 12 months.

The economic analysis consists of cost-effectiveness analyses from two perspectives, society and VA. Data are gathered from the administrative data systems of the site facilities, from patient/proxy surveys, and from public mortality databases. The Health Utilities Index (HUI) is used to evaluate quality of life.

FINDINGS

The study kicked off in September 2003, and patient enrollment began two months later. As of June 1, 2005, nearly 500 patients have been enrolled. Discharge summaries from non-VA inpatient providers have been received for many patients.

IMPACT STATEMENT

CSP 530 holds great promise to significantly benefit veterans with acute renal failure. Pilot studies indicate that intensive dialysis treatment for acute renal failure is likely to significantly improve 60-day mortality. Mortality rates under conventional therapy are typically 45-50% over 60 days, whereas preliminary studies have shown intensive therapy to reduce mortality to 30-40%. The intervention is likely to be cost-effective as well. The extra cost of intensive therapy should be approximately $2,000-3,000 over a 30-day period. If the intensive therapy reduces hospital length of stay, something supported by preliminary studies, then the cost for additional dialysis treatment will be partly or even fully offset by the reduction in hospital days. Even if the intervention does not save costs, it may still be cost-effective by conventional standards.

DURATION OF STUDY
09/03 – 09/08

FUNDING
$16,900,000

PUBLICATIONS
Palevsky PM, O'Connor T, Zhang JH, Star RA, **Smith MW**, for the VA/NIH ATN Study. (2005). Design of the VA/NIH Acute renal failure Trial Network (ATN) Study: Intensive versus conventional renal support in acute renal failure. Clinical Trials 2005;2(5):423-435.

Smith MW, Richardson SS. Dialysis treatment use and costs reported in VA administrative databases. HERC Technical Report 17. Menlo Park, CA: Health Economics Resource Center, Cooperative Studies Program, U.S. Dept. of Veterans Affairs. March 2005.

CSP STUDY 553 - Chemotherapy After Prostatectomy (CAP) for High Risk Prostate Carcinoma: A Phase III Randomized Study

Study Economist: Wei Yu, Ph.D.
HERC

BACKGROUND / RATIONALE

Prostate cancer is the most common epithelial malignancy among men, affecting approximately 190,000 patients per year. The vast majority of men will be diagnosed with clinically localized disease (cT1-T2) and will be offered observation, androgen deprivation, brachytherapy, external beam radiotherapy or radical prostatectomy. A substantial proportion of patients opt for prostatectomy because of preferences for complete removal of tumor, and the ability to provide detailed pathologic staging. VA data indicate that over half of patients with cT1-T2 prostate cancer are treated with prostatectomy within the VA system. A majority of these patients have a risk of relapse of greater than 50% at 5 years with no adjuvant therapy. Identifying interventions that would decrease this risk is an important area for research. The proposed study will determine whether early chemotherapy will reduce the risk of relapse.

OBJECTIVES

The primary objective of the proposed study is to determine whether adjuvant chemohormonal therapy will improve progression-free survival, metastasis-free survival, and overall survival compared to initial observation in patients with clinically localized prostate cancer treated with prostatectomy with high risk features found at prostatectomy (pathologic stage T3-T4, N0M0, Gleason grade >= 7). A standard cost-effectiveness analysis is proposed to find the incremental costs per quality adjusted life year.

RESEARCH PLAN

The economic evaluation will assess costs and quality of life in three stages: (1) at the end of the treatment period, (2) at the end of a follow-up period, and (3) during a patient's lifetime. The treatment period duration is eighteen weeks starting from the intervention or the start of observation, usually right after the prostatectomy. Patient follow-up will occur for a minimum of one year and a maximum of five years depending upon each patient's PSA (prostate specific antigen) level. The rationale for dividing the study into three periods is that quality of life in the two treatment arms may be quite different during the treatment period but may converge one year after treatment. Quality of life may not be different across arms during the follow-up period unless there is relapse. A complete economic evaluation involves modeling the patient's lifetime costs and benefits.

The analytical strategy for the first and the second stages will involve comparing costs and quality of life between the intervention and the control groups. Both bivariate and multivariate methods will be used. The analytical strategy for the third stage will use decision analytic modeling.

The study will be designed from the societal perspective. Thus, costs that are not directly related to medical care will be included. Health care utilization and cost data from both VA and non-VA facilities will be collected. The VA data will be collected from the VA cost database and non-VA data will be collected by obtaining billing statements (UB-92) and discharge summaries from the non-VA facilities. Costs of health care utilization from non-VA facilities will be imputed.

Quality of life will be measured with three instruments: the EuroQol 5-Diminsion (EQ-5D), the Functional Assessment of Cancer Therapy for Prostate Module (FACT-P), and the Subject Significance Questionnaire (SSQ). The EQ-5D is a preference-based, generic multi-attribute utility instrument that measures well being in individuals based on the preferences that society generally associates with a

person's level of functioning at a specific point in time. The EQ-5D instrument consists of two portions: a visual analog scale (VAS) and a five-item utility scale. A single utility score is derived from the EQ-5D that will be used in the cost-effectiveness analysis. The FACT-P is a multi-dimension instrument designed for patients with prostate cancer. Although it cannot generate a single score on quality of life, it is more sensitive than the EQ-5D in assessing quality of life related to prostate cancer treatment. Finally, the SSQ asks the study patients to compare their current state of health with the previous time they completed the quality of life questionnaires. These measurements will enable the study investigators to monitor changes in quality of life between patient follow-up visits.

IMPACT STATEMENT

This study can potentially lead to a reduction in mortality for a cancer that has a high prevalence in VA patients.

DURATION OF STUDY

June 2006 – June 2011

FUNDING

The budget for the economic portion of this study is $585,007. The budget for the full clinical trial is $14,991,596.

ONGOING PROJECTS – PATIENT FOLLOW-UP

CSP STUDY 424 - Clinical Outcomes, Revascularization and Aggressive Drug Evaluation (COURAGE): VA Economic Study

Study Economist: Paul G. Barnett, PhD
HERC

BACKGROUND / RATIONALE

COURAGE is a randomized clinical trial that is examining the effect of cardiac catheterization on the cost and outcomes in heart disease patients who are receiving optimal medical therapy. The trial is enrolling patients with all but the most severe heart disease at 40 centers in the U.S. and Canada, randomizing half to cardiac catheterization, and following them for three years. A total of 3,120 patients will be randomized and followed for a mean of 4.5 years. A major focus of the trial is to determine the incremental cost-effectiveness of the more invasive strategy in dollars per quality adjusted life year (QALY). Additional detailed information will be obtained on participants' quality of life. The goal of the study is to learn whether cardiac catheterization is a cost-effective health care intervention in this type of heart disease patient when optimal medical management is being employed.

OBJECTIVE

It is not known whether percutaneous coronary intervention (PCI) is a cost-effective therapy for patients with moderate ischemic heart disease who also receive optimal medical therapy. Previous trials have compared balloon angioplasty to medical therapy, but they have been too small, have excluded sicker patients, lacked consistent medical care in follow-up, and did not include an economic comparison. The objective of the economic study is to determine if PCI is cost-effective. The VA Economic Study is determining the cost incurred by patients enrolled at VA sites. This cost data will be combined with cost data from other sites and patient preferences in order to find the incremental cost-effectiveness of angioplasty in dollars per quality-adjusted life year (QALY).

RESEARCH PLAN

The COURAGE VA Economic Study is using a variety of health services methods to determine the costs of health care used by COURAGE participants who enroll at VA Medical Centers. Although VA keeps careful account of the resources used by each of its medical centers, it does not does not routinely prepare patient bills, and thus lacks the detailed charge data that researchers in the rest of the U.S. health care sector use to estimate costs. We are evaluating whether DSS can be used to determine costs of the initial treatment, or whether we should estimate costs using parameters from a clinical cost function for Medicare charge data in non-VA hospitals. We are micro-costing these items to ensure that our method is sensitive to the variation in the amount of resources used in the different arms of the trial. We will use gross costing to determine the cost of other hospital stays and ambulatory care. We are identifying prescription medication and its cost from the pharmacy benefit management database.

STATUS

Follow-up will be completed in June 2006.

IMPACT STATEMENT

CSP 424 is the largest trial of PCI conducted to date. Coronary heart disease is the single largest cause of morbidity and mortality among patients in the VA system. Many patients must travel great distances to centers that can provide these services. Results from the trial could result in substantial changes in the management of coronary heart disease, both within VA and in the U.S. and Canadian health care

systems. Approximately $6.0 billion is spent each year on the myocardial revascularization in patients with heart disease. ACE inhibitors, beta-blockers, and especially, the advent of more potent lipid lowering agents, have dramatically improved medical therapy. It has not been determined whether the best coronary interventions, when coupled with the best available medical interventions, are superior to medical interventions alone. This study addresses this important research gap. If patients who do as well with medical therapy alone can be identified, hundreds of millions of dollars in health care costs could be saved.

FINDINGS

Enrollment in this study has now been completed. A draft of the economic methods paper is under review. We extracted information on health care utilization of study participants from VA databases through FY2003, as well as HERC and DSS data on the cost of this care. We are developing methods to identify the cost of cardiac procedures provided to outpatients. We identified the CPT codes used to characterize the procedures provided to study participants on an outpatient basis. We are now in the process of determining the average costs assigned by DSS to visits in which these procedures took place. This information will be useful to finding the cost of non-VA sites. For patients who were hospitalized at the time of randomization, we wished to exclude costs of the stay that were incurred before randomization. Daily costs vary over the course of hospital stays; earlier days in a stay are typically higher cost. We have obtained from the DSS Technical Support Office in Bedford, MA, a detailed database of the cost of most index stays of study participants that took place between 2001 and 2003. These data identify the cost and quantity of intermediate products used in each day of stay. We will develop a model of costs by day of care that we will use to exclude costs incurred before randomization. We will also use these data to validate that DSS cost estimates reflect participants' utilization of diagnostic and revascularization procedures. We obtained clinical data and DSS cost data on VA stays for heart attack, and compared it to Medicare-funded stays of veterans at non-VA hospitals for the same year. This comparison includes our survey data on DSS data quality practices. A manuscript describing this comparison is being prepared. We have obtained data on prescription medications used by participants from the VA Pharmacy Benefits Management System through FY2004. Finally, we are working with the statistical and economic coordinating centers to make sure that VA sites are collecting UB-92 hospital bills with the cost of care for stays by VA patients at non-VA hospitals.

DURATION OF STUDY
10/1999 – 6/2007

FUNDING
$314,586 (budget for economic analysis only)

PUBLICATIONS

Barnett P, **Lin P**, **Wagner T**. (2003). Estimating the cost of cardiac care provided by the hospitals of the US Department of Veterans Affairs. Weintraub W (Ed.) Cardiovascular Health Care Economics. Humana Press.

WS Weintraub, **PG Barnett**, **S Chen**, P Hartigan, et al (2006) Economics methods in the Clinical Outcomes Utilizing Percutaneous Coronary Revascularization and Aggressive Guideline-Driven Drug Evaluation (COURAGE) trial. American Heart Journal (in press)

CSP STUDY 481 - The Home International Normalized Ratio (INR) Monitor Study (THINRS)

Study Economist: Ciaran S. Phibbs, PhD
HERC

BACKGROUND / RATIONALE

Patients on anticoagulation therapy need to be carefully monitored because the effectiveness of the medication is quite sensitive to dietary intake and the consequences of both under and over medication can be quite severe. Current standard practice is to have patients come into an anticoagulation clinic once a month for monitoring and medication adjustment, if necessary. New devices allow for the possibility of patient self-testing (PST) at home, which is more convenient for patients and also makes more frequent testing possible. This study will access if the more frequent testing allowed by PST reduces the number of adverse clinical events.

OBJECTIVE

The purpose of this study is to compare patient self-testing (PST) of anticoagulation intensity to conventional monitoring in the clinic in terms of the number of events (strokes, bleeding or death). Secondary analysis will examine the effects of PST on quality of anticoagulation, health care utilization and cost, quality of life, and cost-effectiveness.

RESEARCH PLAN

This study originally planned to use 32 sites to enroll a sample size of 3,200 patients (1,600 per group) over three years (one for recruitment and two years of follow-up). Only 28 sites were actually recruited as study sites, and enrollment took longer than expected. Recruitment lasted 33 months, resulting in 2923 patients, all being followed until the end of the study. The primary outcome is combined events (serious complications of anticoagulation and death). Cost-effectiveness is a secondary outcome for this study. VA costs will be determined from VA secondary data, with the HERC average costs data sets being the principal data source. Non-VA costs will be tracked using patient self-reports. The Health Utilities Index (HUI) will be used to measure quality of life for the incremental cost-effectiveness analysis. The time horizon for the study will be both the duration of the study and the patient's lifetime.

IMPACT STATEMENT

Prior studies indicate that home Prothrombin Time/International Normalized Ratio (PT-INR) monitors have the potential to improve the safety, quality, and convenience of chronic anticoagulation management. However, these trials were not conducted on veterans, so their results may not generalize to the VA population. Since home monitoring allows more frequent monitoring (as well as increased patient participation in his/her care), we hypothesize that this will lead to more precise anticoagulation control and thus, fewer clinical events.

Given the high costs associated with some of the adverse events, especially strokes, it is hypothesized that home PT-INR monitoring will be more cost-effective than current standards of care. If the intervention works as well as indicated in the small studies reported to date, it may even improve outcomes and reduce costs.

DURATION OF STUDY
8/03 – 3/09

FUNDING
$11,787,448

PUBLICATIONS
Matchar DB, Jacobson AK, Edson RG, Lavori PW, Jack E. Ansell JE, Ezekowitz MD, Rickles F, Fiore L, Boardman K, **Phibbs CS**, Fihn SD, Vertrees JE, Dolor R. (2005). The impact of patient self-testing of prothrombin time for managing anticoagulation: Rationale and design of VA Cooperative Study #481 -- The Home INR Study (THINRS). Journal of Thrombosis and Thrombolysis Jun 2005;19(3):163-172.

CSP STUDY 512 - OPTIMA – A Tri-National Randomized Controlled Trial to Determine the Optimal Management of Patients with HIV Infection For Whom First and Second-Line Active Anti-Retroviral Therapy has Failed

Study Economist: Wei Yu, PhD
HERC

BACKGROUND / RATIONALE

OPTIMA is a tri-national (Canada, UK, USA) randomized controlled trial to determine the optimal management of patients with HIV infection for whom first and second-line highly active anti-retroviral therapy has failed. The trial is using a 2X2 factorial design to evaluate the hypotheses that mega-anti-retroviral therapy (HAART) (compared to standard-ART) and an anti-retroviral drug-free period (compared to no anti-retroviral drug-free period) will delay the occurrence of new or recurrent AIDS events or death and will be more cost-effective in treating HIV-infected individuals previously exposed to HAART drugs from the current three main classes. This is the first large-scale, multi-center, randomized controlled trial to compare the relative efficacy of these different therapeutic strategies.

OBJECTIVE

The health economics analysis will evaluate the cost-effectiveness and short-term resource consumption of each alternative treatment strategy for treating HIV patients who have failed standard anti-retroviral therapy.

RESEARCH PLAN

The cost-effectiveness of the interventions will be estimated using the patients' life span as the time horizon for the analysis. Standard methods will be used. Sites in all three countries will gather a common set of utilization and outcomes data. To capture differences in patients' preferences to medical treatments across the three countries, three instruments are used to measure quality of life: EQ5D, Health Utility Index (HUI), and computer-based assessment. EQ5D is a commonly used instrument in European countries, HUI has been widely used in Canada, and the computer-based assessment has been used in studies in the United States. A Markov or statistical model will be developed to project trial participants' lifetime cost and outcomes for a cost-effectiveness analysis. These data will be used to create a separate economic analysis for each country. Each analysis will reflect the country's guidelines for accepted practices for performing for cost-effectiveness studies, sources of costs for pharmaceuticals and health services, factors affecting lifetime survival, and discount rate. In addition to country specific analysis, we will employ statistical methods to investigate the extent to which cost-effectiveness differs between countries.

IMPACT STATEMENT

The VA System cares for approximately 19,000 HIV patients who have access to HIV-knowledgeable health care providers, to the full spectrum of approved antiretroviral medications, and to laboratories that perform virologic and immunologic testing. It is estimated that 30-40% of HIV patients treated at VA facilities have detectable viral loads.

HAART therapy has been extremely beneficial but increasing numbers of patients are being failed by these therapies due to resistance and long-term toxicity. These patients are posing an increasing therapeutic dilemma. Clinicians currently utilize the different therapeutic approaches to be studied in this trial without any clinical trials-based evidence. This study has the potential provide information on benefits and risks of the different therapeutic strategies.

DURATION OF STUDY
06/2001 -09/2007

FUNDING
$1,038,312 (budget for economic analysis only)

PUBLICATIONS

Munakata J, Woolcott J, Anis A, Schulpher M, **Yu W**, **Sanders GD**, Bayoumi A, **Gulbinas V**, Philips Z, **Owens DK**. Design of a Prospective Economic Evaluation for a Tri-National Clinical Trial in HIV Patients (OPTIMA), Abstract, Controlled Clinical Trials, 2003

Joyce V, **Aalfs SSA, Sundaram V**, **Hill AK**, **Baker F**, Sanders G, Munakata J, Holodniy M, Sculpher M, Anis A, **Yu W, Owens DK** and the OPTIMA Team Utility-based Assessments of Quality of Life in a Randomized Trial of Antiretroviral Therapy in Advanced HIV Disease, Presented at the Society for Medical Decision Making conference, October 2004

Aalfs SSA, Guh D, Singer J, **Joyce V, Sundaram V,** Munakata J, **Hill AK**, Sun H, Griffin SC, Sanders GD, Bayoumi A, Holodniy M, Brown S, Sculpher MJ, **Yu W, Owens DK**, Anis A, and the OPTIMA Team. The Impact of AIDS-Related Events and Non-AIDS serious Adverse Events on Health-Related Quality of Life in a Multinational Trial of Antiretroviral Therapy, Poster at the Society for Medical Decision Making conference, October 2004.

PRIMARY ANALYSIS AND MANUSCRIPT WRITING

CSP STUDY 027 - Economic Study of 18-F Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) Imaging in Patients with Solitary Pulmonary Nodules

Study Co-Principal Proponents: Paul G. Barnett, PhD
HERC

Michael K. Gould, MD, MSc
Douglas K. Owens, MD, MSc
Gillian Sanders, PhD

BACKGROUND / RATIONALE

When chest x-rays reveal a solitary pulmonary nodule (SPN), malignancy must be excluded or promptly identified if surgical treatment is to be timely. Computed tomography (CT) is insufficiently specific to avoid biopsy of patients with negative results. Positron Emission Tomography (PET) using 18-F-Fluorodeoxyglucose (FDG) may be sufficiently specific to avoid invasive biopsy in when results are negative. The cost-effectiveness of FDG-PET diagnostic strategies has not been fully evaluated.

OBJECTIVE

This study is evaluating the cost-effectiveness of alternate management strategies, including the use of FDG-PET scans, for patients with solitary pulmonary nodules. It will identify patient populations and clinical circumstances in which FDG-PET is most cost-effective. The study is also addressing the cost-effectiveness of FDG-PET for staging the mediastinum of patients with non-small cell lung cancer (NSCLC). A new economic sub-study is examining cost and utilization in subgroups of study participants. It is examining the consequences of watchful waiting and biopsy, and studying whether PET results are associated with differences in the cost of subsequent health care. The study is also combing administrative data with trial observations to examine how well pre-test characteristics, including smoking history, cancer history, and nodule characteristics, identify patient risk of lung cancer.

RESEARCH PLAN

We are constructing decision models to find the impact of all reasonable sequences of diagnostic strategies with and without PET. One decision model evaluates strategies for diagnosis of SPN, the other evaluates mediastinal staging in patients with NSCLC. The SPN model includes 40 possible sequences of five diagnostic interventions: CT, PET, transthoracic needle biopsy (TTNB), surgery, and observation with serial chest radiographs. We are surveying VA clinical centers to determine the cost of PET scans. The models are being constructed with data from meta-analysis, literature review, and data on the natural history of untreated lung cancer. We are analyzing Medicare claims data merged with clinical information from the National Cancer Institute's Surveillance, Epidemiology and End-Results (SEER) registry to estimate life expectancy and health care costs associated with different stages of lung cancer.

IMPACT STATEMENT

It is difficult to diagnose a solitary pulmonary nodule found in a chest x-ray. Between 15% and 75% of nodules prove to be malignant. Surgery is diagnostic and the definitive treatment of resectable nodules, but is unnecessary when the lesion is benign. Needle biopsy is invasive, potentially risky, and frequently non-diagnostic. Watchful waiting avoids unnecessary surgery, but may cause delay when speedy treatment is essential. Positron emission tomography (PET) with 18-fluorodeoxyglucose (FDG) is a potentially useful but expensive test. This economic model will determine if the high cost of PET is justified. Improved diagnosis will save costs by avoiding unnecessary resection of benign nodules; it could also speed diagnosis, prolonging the lives of patients with malignancy. The project will also determine if PET is worth using in the management of patients with non-small cell lung cancer.

FINDINGS

We published papers on the cost of PET scans and a decision model that compared 40 clinically plausible management strategies for patients with solitary pulmonary nodules. We also published a meta-analysis of 39 studies that examined the accuracy of FDG-PET for identifying mediastinal lymph node metastasis in patients with non-small cell lung cancer.

We updated the model of PET for pulmonary nodule diagnosis by using preliminary estimates of conditional test performance for PET and computed tomography (CT). This model is now being updated with the final results of PET test performance from CSP 27. We developed a model to identify the most cost-effective practices for mediastinal staging in two commonly encountered clinical scenarios: patients without lymph node enlargement on CT and patients with enlarged nodes in mediastinal stations accessible to bronchoscopy. Meta-analyses of bronchoscopy and mediastinoscopy are being finished to provide accurate parameters needed to complete this model. We combined data with VA cost and utilization databases with data from study forms for an observational study of patients with solitary pulmonary nodules. We develop a model of the pre-test probability of lung cancer, information needed to make the most cost-effective use of PET for diagnosing SPN. This work is under review. We have characterized the treatments received and costs incurred by study participants. A manuscript on the treatment costs following SPN screening by PET is being revised for submission.

DURATION OF STUDY
6/1998 – 10/2005

FUNDING
$472,477 (budget for economic analysis only)

PUBLICATIONS

Berger M, **Gould MK**, **Barnett PG**. (2003). The cost of positron emission tomography in six United States Veterans Affairs hospitals and two academic medical centers. American Journal of Roentgenology: 181(2):359-65.

Gould MK, Kuschner WG, Rydzak CE, et al. (2003). Test performance of positron emission tomography and computed tomography for mediastinal staging in patients with non-small-cell lung cancer: a meta-analysis. Annals of Internal Medicine: 139(11), 879-892.

Gould MK, MacLean C, Kuschner W, Rydzak C, **Owens D**. (2002). Accuracy of positron emission tomography for diagnosis of pulmonary nodules and mass lesions: A meta-analysis. Journal of the American Medical Association: 7, 914-924.

Gould MK, **Sanders GD**, **Barnett P**, Rydzak CE, Maclean CC, McClellan MB, **Owens DK**. (2003). Cost-effectiveness of alternative management strategies for patients with solitary pulmonary nodules. Annals of Internal Medicine: 138(9), 724-735.

Barnett PG, **Berger M** (2003). Indirect Costs of Specialized VA Mental Health Treatment. HERC Technical Report #6. Health Economics Resource Center. Menlo Park, CA. April 2003.

Gould, M, L Ananth, PG Barnett (2006). A clinical model to estimate the pre-test probability of lung cancer in patients with solitary pulmonary nodules (under review)

CONTINUING ACTIVITY

CSP STUDY 006 - Effectiveness of Geriatric Evaluation and Management Units (GEMU) and Geriatric Evaluation and Management Clinic (GEMC)

Study Economist: Ciaran S. Phibbs, PhD
HERC

BACKGROUND / RATIONALE

Geriatric Evaluation and Management Units (GEMU) are dedicated hospital units where a multidisciplinary team provides comprehensive geriatric assessment, detailed treatment plans, and attention to the rehabilitative needs of older patients. Geriatric Evaluation and Management Clinics (GEMC) provide similar services on an outpatient basis. Early, single site, clinical trials reported that GEMUs dramatically reduced mortality. More recent studies have reported mixed results.

OBJECTIVE

This large, multi-site, clinical trial was designed to definitively determine the effect of GEM care on mortality. The study evaluated both inpatient and outpatient GEMs using a 2x2 randomized design. Secondary objectives included cost-effectiveness analysis and a description of health care utilization and the costs of these services.

RESEARCH PLAN

Patients were recruited from inpatient units when they were medically stable. They were randomized to receive GEMU or usual inpatient care (UCIP). At discharge to home, a second randomization assigned patients to usual outpatient care (UCOP) or the GEMC. Patients were assessed at 3-month intervals for one year. Follow-up data included SF-36 scores, activities of daily living (ADLs), and use of non-VA nursing home care. Utilization of VA care was tracked using VA databases.

HERC Clinical Panel members Drs. Mary Goldstein and Alan Garber directed an approved sub-study of the GEM trial that obtained direct utility measures for the possible health states of the GEM trial from a sample of Kaiser patients. This project used the sub-study results to obtain utilities for each patient in the GEM study. These were linked with the cost and utilization data from the GEM study to conduct an incremental cost-effectiveness analysis.

For the utility measures sub-study, ADLs were administered to subjects, in addition to direct utility measurement. Various combinations of ADLs from the GEM study were used to determine the health states for which utilities were measured. Since it was not possible to directly measure the utility for all possible combinations of ADLs, a model was developed to map various combinations of ADLs to utilities. This model was applied to the data from the GEM study to obtain a utility measure for each patient.

IMPACT STATEMENT

With a large and growing elderly population, the provision of geriatric care is a major concern to the VA. The VA aggressively adopted the GEM model of care based on the results of the early clinical trials. This large clinical trial found neutral results, no added benefit or costs. Since GEM care does seem to improve patient satisfaction, continuation of GEM care is warranted. Information on how the costs were distributed across study subjects and between types of health care may be useful to VA managers.

FINDINGS

The study enrolled 1388 patients out of a target enrollment of 1400 patients at 11 sites. The main paper of the GEM study was published in the New England Journal of Medicine (Cohen, et al., 2002) and reported a small, but statistically insignificant reduction in the costs of care for patients treated in GEM units. There was no difference in mortality by arm of the study and the point estimates were virtually identical. Most of the differences in outcomes, as measured by the SF-36, Activities of Daily Living Scale (ADLs), or Instrumental Activities of Daily Living Scale (IALDs), were not statistically significant, but GEM patients did do better on two of the components of the SF-36.

As might be expected, given the limited differences in other outcomes measures, there was no significant difference in utilities. Nursing home placement was not incorporated into the utility assessment, which may have influenced this result. There were statistically insignificant mean cost savings of $1,027 (p=0.29) per patient for the GEMU and $1665 (p=0.69) per patient for the GEMC. A complete cost-effectiveness analysis, including bootstrap estimates of the confidence area, also showed no effect. An examination of the details of resource utilization, found that GEMU care was associated with a reduction in the use of nursing home care (odds ratio 0.65, p=0.001). 127 of the 694 patients in the GEMU arm were admitted to a nursing home in the one-year follow-up period, compared to 177 out of 694 for those patients with UCIP. The average nursing home expenditures for GEMU patients was $1,975 less than for UCIP (p=0.002). GEMC had not effect on the use of nursing home care. If reduced use of nursing home care is considered a benefit, the GEMU care can be considered cost-effective; it improved outcomes with no increase in costs.

DURATION OF STUDY
01/1995 - 01/2002

FUNDING
$4,118,901 (Total trial budget)

PUBLICATIONS
Cohen H, Feussner J, Weinberger M, Carnes M, Hamdy R, Hsieh F, **Phibbs C**, Lavori P. (2002). A controlled trial of inpatient and outpatient geriatric evaluation and management. New England Journal of Medicine: 346, 905-912.

Phibbs CS, Holty JEC, Goldstein MK, Garber AM, Wang Y, Feussner JR, Cohen HJ. (2005). The effects of geriatric evaluation and management on nursing home use and health care costs: results from a randomized trial. Medical Care: 2006;44(1):91-95

PRESENTATIONS
Phibbs CS, Holty JKC, Goldstein MK, Garber AM, Wang Y, Feussner JR, Cohen HJ. The Effects of Geriatric Evaluation and Management On Nursing Home Use and Health Care Costs: Results From A Randomized Trial. Presented at the Veterans Affairs Health Services Research and Development Service National Meeting, February 2005, Baltimore, MD.

CSP STUDY 385 - Urgent Revascularization in Unstable Angina (AWESOME)

Study Economists: Kevin Stroupe, PhD
Hines CSPCC

Paul G. Barnett, Ph.D.
HERC

BACKGROUND / RATIONALE

Coronary revascularization is among the procedures most frequently performed in the United States' health care system. Coronary Artery Bypass Grafts (CABG) are more expensive than percutaneous coronary intervention (PCI) procedures, but PCI is more likely to require a subsequent revascularization. The Angina With Extremely Serious Operative Mortality Evaluation (AWESOME) compared PCI to CABG for urgent revascularization of high surgical risk patients, who had been excluded from previous randomized trials.

OBJECTIVES

This economic sub-study will compare the costs, survival and cost-effectiveness of PCI to CABG in high risk, medical-refractory patients in need of emergent revascularization over three and five years of follow-up.

RESEARCH PLAN

This randomized controlled trial examined urgent revascularization of medically refractory, high-risk myocardial ischemia patients, a group largely excluded from previous trials. A total of 454 men with medically refractory, high-risk myocardial ischemia were randomized, and 445 were available for the economic analysis: 218 underwent percutaneous coronary intervention and 227 underwent coronary artery bypass grafting. This economic study will follow participants in the AWESOME trial in VA cost and utilization datasets and the VA BIRLS death file. The cost of hospital stays for heart disease will be estimated using a cost function specific to cardiac care. HERC average cost estimates will be used for other care; for care prior to the creation of the HERC dataset (prior to 1998), the HERC method will be applied. The joint statistical significance of cost and outcomes will be assessed with a bootstrap analysis.

IMPACT STATEMENT

Coronary revascularization is an expensive technique and among the most frequently performed in the United States, with about 515,000 percutaneous coronary intervention (PCI) procedures and 306,000 coronary artery bypass grafts (CABG) performed in 2002. CABG is a much more expensive procedure, but PCI often needs to be repeated. Medically refractory, high-risk myocardial ischemia patients are at high risk for major complications or death from surgery and have largely been excluded from other randomized controlled trials examining whether CABG is more effective or cost-effective.

FINDINGS

PCI was found to be less costly and more effective for the urgent revascularization of medically refractory, high-risk patients. After 3 years, average total costs were $63,896 for PCI versus $84,364 for CABG patients, a difference of $20,468 (95% confidence interval [CI], $13,918 to $27,569). The probability of survival at 3 years was 0.82 for PCI versus 0.79 for CABG patients (P = 0.34). Bootstrap analysis revealed that after 3 years, PCI was less costly and more effective 92.6% of the time. After 5 years, PCI was $18,732 less costly (95% CI, $9,873 to $27,831). The probability of survival at 5 years was 0.75 for PCI patients versus 0.70 for CABG patients (P = 0.21). Bootstrap analysis revealed that after 5 years, PCI

remained less costly and more effective 89.4% of the time.

DURATION OF STUDY
2/1995 – 10/2005

PUBLICATIONS
Stroupe, KT, DA Morrison, MA Hlatky, **PG Barnett**, L Cao, C Lyttle, DM Hynes, WG Henderson. Cost-effectiveness of coronary artery bypass grafts versus percutaneous coronary intervention for revascularization high-risk patients. Circulation (in press).

COMPLETED PROJECTS

CSP STUDY 020 - Cost and Outcome of Telephone Care - Pilot

Study Economist: Ciaran S. Phibbs, PhD
HERC

BACKGROUND / RATIONALE

Enhanced clinician-patient communication can help improve health outcomes and lower health care costs. Traditionally such communication has taken place during a face-to-face visit. A single site VA study that randomized half of the patients to receive more frequent, physician-initiated “telephone appointments” in place of some clinic visits reported lower utilization and costs with no effect on patient health. The two site pilot study for CSP 020 was to test the feasibility of a multi-site VA trial of this mode of treatment.

OBJECTIVE

The objective of the pilot study was to test the feasibility of conducting this study and to obtain preliminary results to guide the sample size determinations for the main study.

RESEARCH PLAN

Patients were randomized to receive usual primary care or telephone care. Patients in the telephone care arm were to have the time between face-to-face visits double, with three scheduled, physician-initiated, telephone contacts in between visits. Data were collected on patient’s satisfaction and health status and on their utilization of VA and non-VA health care services.

IMPACT STATEMENT

If the main study had confirmed the findings of the earlier studies, this would represent an opportunity for VA to both improve outcomes and decrease costs. Given the resource constraints in VA, this would allow VA to provide additional services to veterans. The results of this study would also be applicable to health care outside of the VA.

FINDINGS

Although the interval to the next face-to-face visit was doubled for the telephone care patients after the initial clinic visit, the interval between visits was the same for both telephone care and usual care patients for all subsequent visits. Thus, telephone care became an additional service, instead of substituting for face-to-face visits. There was no difference between groups in self-reported health status, hospital admission, mortality, total number of clinic visits, number of outpatient laboratory tests, or number of outpatient radiological tests. Telephone care patients did have fewer unscheduled visits than usual care patients. While the study didn’t find any differences, the intervention was not implemented as designed. Because the effect on utilization and costs was thought to have come from reduced face-to-face contact, these results were not a valid test of the hypothesis.

DURATION OF STUDY
9/1995 – 2/1999

FUNDING
$724,343

PUBLICATIONS

Welch HG, Johnson DJ, Edson R writing for the Telephone Care Study Group. (2000). Telephone care as an adjunct to routine medical follow-up, a negative randomized trial. Effective Clinical Practice: 3:123-130.

CSP STUDY 368A - VA Non Q-Wave Infarction in Hospital (VANQWISH): Economic Study

Study Economist: Paul G. Barnett, PhD
HERC

BACKGROUND / RATIONALE

The VA Non-Q-wave Infarction Strategies in Hospital (VANQWISH) trial demonstrated that a conservative, ischemia-guided strategy was safe and effective for management of non-Q-wave myocardial infarction. It was not known whether this strategy was cost-effective.

OBJECTIVE

This project applied health services methods to find total cost incurred by study subjects and to analyze trial data from an economic perspective.

RESEARCH PLAN

We studied 876 of the 920 VANQWISH participants who enrolled at VA sites and tracked their use of VA hospitals and outpatient clinics in utilization databases. We estimated cost of initial VA hospital stays with a function estimated with data from the Myocardial Infarction Triage and Intervention (MITI) registry. We used average cost methods to estimate the cost of subsequent care, using a Medicare based rate for acute hospital stays and VA derived estimates for outpatient care and non-acute inpatient stays. Data also included cost-adjusted charges of non-VA hospital stays. We employed a bootstrap method to estimate the variance of the cost-effectiveness result.

IMPACT STATEMENT

Non-Q wave infarcts account for approximately 40% of new heart attacks. We found conservative strategy saved $2,186 per heart attack treated. This cost difference applied to 40% of 10 thousand VA stays for myocardial infarction represents $9 million in annual health care cost. If results can be generalized throughout the U.S. health care system, where 750 thousand new heart attacks are treated annually, the difference represents an annual savings of $650 million.

FINDINGS

Subjects randomized to the invasive strategy incurred an average of $41,893 in cost, significantly more than the $39,707 cost incurred by the conservative strategy group (p=.037). The initial hospital stay cost an average of $19,256 for the invasive group, significantly more than the $14,733 mean cost of the initial stay for the conservative group (p=.0001). The mean cost of follow-up care was not significantly different ($22,626 for invasive group vs. $24,974 for conservative strategy). Conservative strategy had lower all-cause mortality (relative risk ratio of .72) but this difference was not significant (p=.058). The conservative strategy was significantly more cost-effective than the invasive one (p=.044). This result held over a wide range of critical cost-effectiveness threshold values, for a different discount rate, and for the alternate cost method. We found a conservative, ischemia-guided strategy more cost-effective than the routine use of invasive procedures in the management of non-Q wave infarcts.

DURATION OF STUDY
7/1998 - 2/2002

FUNDING
$78,000 (Economic study only)

PUBLICATIONS
Barnett P, **Chen S**, Boden W, Chow B, Every N, Lavori P, Hlatky M. (2002). Cost-effectiveness of conservative management of non Q-wave myocardial infarction. Circulation: 105, 680-684.

CSP STUDY 420 - Analysis of Health Care and Work among Veterans with PTSD

Study Economist: Mark W. Smith, PhD
HERC

BACKGROUND / RATIONALE

This project will study the impact of Post Traumatic Stress Disorder (PTSD) symptoms and their severity on use of health services and on economic outcomes. It relates employment outcomes to health care use within VA and from other providers. Although many studies have linked economic outcomes to mental health, here we have the unusual ability to link economic outcomes to several specific clinical measures. It will also shed new light on the extent to which veterans with PTSD receive services from both VA and non-VA providers, and how the mix of VA and non-VA services relates to the type and severity of PTSD symptoms.

OBJECTIVE

The purpose of CSP 420 was to test a novel approach to group therapy for veterans with posttraumatic stress disorder (PTSD). In the CSP 420 protocol, data were collected on subjects' employment history and on their use of health care services from VA and from other providers.

The first part of this study consisted of an investigation of employment outcomes, focusing on how variation in PTSD symptoms correlated with variations in employment status and earnings. The next step will be to extract VA health care utilization data for study participants. These data will include all inpatient and outpatient encounter records for the 24 months prior to and 24 months following the date of randomization into CSP420. We will then merge VA pharmacy data onto the analytic file. We will ask the Pharmacy Benefits Management Strategic Healthcare Group (PBM/SHG) to create an extract of outpatient pharmacy data from its PBM V3.0 database. The final source of VA administrative data will be the Fee Basis Files, which records care provided by non-VA providers but paid by VA.

RESEARCH PLAN

Costs must be attributed to VA and non-VA health care events. We will assign national-average costs derived by the VA Health Economics Resource Center.

Four analyses are planned: (1) the relative importance of PTSD symptoms scores and patient functional scores in predicting health care use and expenditures; (2) what factors predict non-VA health care use and expenditures; (3) the relation of economic outcomes (employment status and income) to PTSD symptom scores and treatment modality, and (4) two issues about facility-level variation: how much variation in patient outcomes is explained by the variation in treatment site, and whether treatment in one site versus another explains more variation in patient outcomes than the patients' own characteristics.

Standard regression models will be employed for the utilization models, including probit or logit for binary outcomes (e.g., presence of an inpatient stay) and negative binomial models for integer-valued outcomes (e.g., number of outpatient visits). Depending on preliminary analyses, the expenditure models will be estimated with one of several linear and nonlinear regression models.

IMPACT STATEMENT

Of the total veteran population, 1.2-2.4 million males and 140,000-250,000 females can conservatively be estimated to have had PTSD during their lifetimes. The VHA systems of specialized outpatient care for

PTSD report an annual workload of approximately 200,000 veterans. By obtaining a better understanding of the link between PTSD symptoms and the use of VA and non-VA health care use, we may improve the ability of VHA managers to forecast facility needs and expenses due to changes over time in the population of persons with PTSD. An investigation of the link between PTSD symptoms and economic outcomes may lead to improvements in services for persons with PTSD, whether within VA or from other sources.

FINDINGS

In the employment study we found that veterans with more severe symptoms were more likely to work part-time or not at all. Among workers, more severe PTSD symptoms were weakly associated with having a sales or clerical position. Conditional on employment and occupation category, there was no significant relation between PTSD symptom level and earnings. Alternative PTSD symptom measures produced similar results. Our findings suggest that even modest reductions in PTSD symptoms may lead to employment gains, even if the overall symptom level remains severe.

DURATION OF STUDY
01/2002 - 06/2005

FUNDING
No additional funding for economic analysis.

PUBLICATIONS
Smith MW, Schnurr P, Rosenheck R. Employment outcomes and PTSD symptom severity. Mental Health Services Research 2005;7(2):89-102

CSP STUDY 1008 - The Pharmacoeconomics of Buprenorphine Treatment of Opiate Dependence

Principal Investigator: Paul G. Barnett, PhD
HERC

BACKGROUND / RATIONALE

This pharmacoeconomic study examined if the combination of buprenorphine and naloxone would be a cost-effective treatment for opiate dependence. The efficacy of buprenorphine was estimated in a meta-analysis of trials comparing buprenorphine to methadone maintenance. A dynamic model was created to estimate the effect of expanded access to opiate substitution therapy on the progress of the HIV epidemic. The prices and conditions under which buprenorphine would be considered cost-effective were determined. This work is companion to the randomized trials of buprenorphine coordinated by the Perry Point CSPCC.

OBJECTIVE

The objective of this project was to determine the threshold price at which the combination of buprenorphine and naloxone would be considered a cost-effective opiate substitution therapy.

RESEARCH PLAN

A meta-analysis of clinical trials compared the effectiveness of buprenorphine to methadone in terms of urinalysis for opiates and retention in treatment. Literature review and analysis of administrative data were used to determine cost of treatment and the effects of methadone maintenance on the morbidity and mortality of opiate addicts. A multi-compartmental mathematical model was used to estimate the effect of changes in risk behavior on the progress of the HIV epidemic. The study used incremental cost-effectiveness analysis. Effectiveness was considered as the effect of treatment on illicit drug use, HIV risk behaviors, and morbidity and mortality. Since complete data on the effects of this drug are not available, mathematical models were used to simulate outcomes. The cost-effectiveness analysis determined the threshold price at which decision makers will be willing to adopt the drug.

IMPACT STATEMENT

There are 1 to 1.5 million injection drug users (IDUs) in the U.S. and between 600,000 and 800,000 who are addicted to heroin. Treatment capacity is limited, however; there were only 179,000 patients enrolled in U.S. methadone treatment programs in 1998. Injection drug use is an important cause of the spread of human immunodeficiency virus (HIV), and the principal route of HIV transmission among heterosexuals in the United States. More than 35% of new HIV cases are among injection drug users (IDUs), their sexual partners, and offspring. Buprenorphine is a promising opiate substitution therapy that could be dispensed outside of specialized treatment programs, reducing injection drug use and the spread of HIV.

FINDINGS

We created a multi-compartmental model to determine the effect of expansion of drug treatment capacity on the progress of the HIV epidemic. Compared to drug free treatment, access to methadone maintenance has an incremental cost-effectiveness ratio of $5,915 per life-year gained, a ratio that is lower than that of most common medical therapies. Using the criteria for judging medical care programs, we found that substance abuse treatment may be regarded as a highly cost-effective means of preventing death. This work was published in the American Journal of Public Health; a more technical paper was

published by Management Science. This paper set the groundwork for the pharmacoeconomic evaluation of buprenorphine.

Original data from five clinical trials comparing buprenorphine to methadone were analyzed and combined in a meta-analysis that was published in Addiction. We incorporated this information in the epidemic model to find the cost and effectiveness of maintenance therapy of buprenorphine. It was determined that if buprenorphine is sold for less than $15 per dose, it will be regarded as cost-effective if medium to high values are set on the quality of life of injection drug users and those in buprenorphine maintenance. At price of less than $5 a dose, it will be considered cost-effective regardless of the quality of life values employed. This paper was also published by Addiction. Other research on this project includes a literature review of methadone cost-effectiveness published in Mt. Sinai J Med.

DURATION OF STUDY
12/1995-4/2001

FUNDING
$272,975 (Economic analysis only)

PUBLICATIONS
Barnett, P. (1999). The cost-effectiveness of substance abuse treatment. Current Psychiatry Reports: 1(2), 166-171.

Barnett, P. (1999). The cost-effectiveness of methadone maintenance as a health care intervention. Addiction: 94(4), 479-488.

Barnett P, **Hui S**. (2000). The cost-effectiveness of methadone maintenance. Mount Sinai Journal of Medicine: 67(5-6), 365-374.

Barnett P, Rodgers J, Bloch D. (2001). A meta-analysis comparing buprenorphine to methadone for treatment of opiate dependence. Addiction: 96, 683-690.

Barnett P, Zaric G, Brandeau M. (2001). The cost-effectiveness of buprenorphine maintenance for opiate addiction in the U.S. Addiction: 96, 1267-1278.

Zaric G, **Barnett P**, Brandeau M. (2000). HIV transmission and the cost effectiveness of methadone maintenance. American Journal of Public Health: 90(7), 1100-1111.

Zaric G, Brandeau M, **Barnett P**. (2000). Methadone maintenance and HIV prevention: A cost-effectiveness analysis. Management Science: 46(8), 1013-1031.

OTHER STUDIES PLANNED

CSP STUDIES PLANNED BY HERC IN PREVIOUS YEARS, BUT NOT FUNDED

Study	Year	Status
CSP #020 Cost and Outcome of Telephone Care, Main Study	1997-1998	Not submitted to CSEC, PI left VA
CSP #445 Effect of Treatment of Sleep Apnea with Oxygen on Hospitalization and Survival of Patients with Stable Heart Failure	1999	Approved, not funded
CSP #455 A Double-Blind, Randomized, Placebo-Controlled Trial to Evaluate the Cost-Effectiveness of Alternative Management Strategies in Patients with Dyspepsia	1999	Approved, not funded
CSP #473 Cost and Outcome of Varying Primary Care Revisit Intervals	1999	Not approved
CSP #490 Efficacy and Safety of Testosterone in Elderly Men (ESTEEM)	1999-2001	Approved, not funded
CSP #503 Improving Outcomes Among Patients with Co-Occurring Depression and Diabetes	2003	Stopped in planning
CSP #509 Clopidogrel and Aspirin Versus Aspirin Stroke Study: A Tri-National Collaboration	2001	Stopped in planning
CSP #529 A Randomized Trial Comparing Tumor Necrosis Factor-Inhibitor, Methotrexate, and Placebo for Ankylosing Spondylitis	2004	Approved, not funded

SECTION II. – STATUS OF HERC

The Health Economics Resource Center (HERC) is the economic coordinating center for the Cooperative Studies Program (CSP). It coordinates the economic analyses for CSP studies, advises other CSP economists on their work, and improves the infrastructure of VA health economics research. HERC conducts economic analyses of clinical trials. HERC receives additional core funding from the Health Services Research & Development (HSR&D) Service and project-specific funding from VA, NIH, and private foundations.

A. Activities of the CSP Economics Coordinating Center

1. Evaluation of CSP Planning Letters for Inclusion of Economic Analyses

HERC coordinates the evaluation of new CSP studies to determine which should include an economic analysis. Historically, CSP did not have standard procedures or criteria for this decision. HERC now receives a copy of all planning letters submitted to CSP. HERC has two economists independently review each planning letter. Based on these reviews, a recommendation on whether to include economic evaluation is made to the Director of the statistical coordinating center that is planning the study. The goal of this effort is to make the best use of CSP resources and only include an economic analysis when it can have the greatest impact.

In the last year, four planning letters were reviewed (see table). Full economic analysis was recommended for two of these studies. The decision about economic analysis for one study has been deferred until after the first planning meeting. One study being planned will be submitted to CSSMRB for review at the October 2006 meeting and the other is just starting the planning process.

HERC developed criteria for determining when economic analysis should be included in VA cooperative studies. In 2003 HERC lead a comprehensive review of the economic analyses of past and current CSP trials, including those where economic analyses were specifically rejected. The reasons for including or excluding an economic analysis were considered and each study was assigned a score on a three-point scale for importance of including an economic analysis. The results of this review were used to draft guidelines on when economic analysis should be included in CSP studies. [1] These guidelines assist the economist reviewers of CSP planning letters.

Results of HERC Reviews of CSP Planning Letters, 2005-2006

CSP Planning Letter	CSPCC	Economist Reviewers	Recommendation of Economic Review
CSP 565: Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy	West Haven	Ciaran Phibbs	Include economic analysis
CSP 566: Neuropsychological and Mental Health Outcomes of OIF: A Longitudinal Cohort Study	West Haven	Ciaran Phibbs	Defer decision until after first planning meeting
CSP 568: Improving Quality of Life for Patients with Malignant Bowel Obstruction	Palo Alto	Paul Barnett	Include economic analysis
CSP 569: A Twin Study of Course and Consequences of PTSD in Vietnam Era Veterans	Seattle	Mark Smith	No economic analysis

2. Studies Planned by HERC Economists

In the past year HERC economists helped plan five studies, two of which has been reviewed by CSSMRB. CSP 555 was approved for funding and will start recruiting patients in the summer of 2006. CSP 560 was approved for a pilot study and will enter the start-up phase in July 2006. The remaining three studies have not yet been reviewed by CSSMRB.

Studies Planned by HERC Economists, 2005-2006

Study	CSPCC	Economist	Status
CSP 555: Impact of Long-Acting Injectible Risperidone on Cost-Effectiveness of Treatment for Veterans with Schizophrenia	Boston	Paul Barnett	Pre-kickoff
CSP 562: Randomized Trial of Actinic Keratosis Treatment Modalities for the Prevention of Basal and Squamous Cell Carcinoma of the Skin	Boston	Ciaran Phibbs	To CSSMRB Fall 2006
CSP 560: Effectiveness of an education, self-management, and case management intervention to prevent COPD exacerbations and hospitalizations	Boston	Mark Smith (planning); Todd Wagner (study)	Pilot study approved; start-up to begin July, 2006
CSP 565: Combination Angiotensin Receptor Blocker and Angiotensin Converting Enzyme Inhibitor for Treatment of Diabetic Nephropathy	West Haven	Patsi Sinnott	To CSSMRB Fall 2006
CSP 568: Improving Quality of Life for Patients with Malignant Bowel Obstruction	Palo Alto	Paul Barnett	First planning meeting June 2006

3. New Cooperative Studies Involving HERC Economists

HERC economists have helped plan four new cooperative studies that are set for kick-off in the coming months. These include studies of an innovative but expensive treatment for rheumatoid arthritis (CSP 551), evaluation of a long-acting antipsychotic drug for treatment of schizophrenia (CSP 555), evaluation of robot-assisted rehabilitation of patients who have a stroke (CSP 558), and an evaluation of a program to prevent the acute exacerbations of Chronic Obstructive Pulmonary Disease (CSP 560).

New Cooperative Studies of HERC Economists

Study	CSPCC	Economist
CSP 551: Rheumatoid arthritis: comparison of active therapies in patients with active disease despite methotrexate therapy	Boston	Ciaran Phibbs
CSP 555: Impact of Long-Acting Injectible Risperidone on Cost-Effectiveness of Treatment for Veterans with Schizophrenia	Boston	Doug Leslie, Paul Barnett
CSP 558: Robotic Assisted Upper Limb Neurorehabilitation in Stroke Patients	West Haven	Todd Wagner
CSP 560: Effectiveness of an education, self-management, and case management intervention to prevent COPD exacerbations and hospitalizations	Boston	Mark Smith

4. Ongoing Studies Involving HERC Economists

HERC economists worked on seven CSP studies that are actively recruiting and following patients. These include studies of treatment strategies for HIV (CSP 512), heart disease (CSP 424), a comparison of radial artery to saphenous vein grafts for heart bypass surgery (CSP 474), a study integrating smoking cessation into the mental health care of Post Traumatic Stress Disorder (PTSD) patients (CSP 519), a study of intensive renal support for acute renal failure (CSP 530), and an evaluation of home monitoring of anti-coagulation therapy (CSP 481). In the past year, enrollment began for a study of prostate cancer therapy (CSP 553).

Ongoing Cooperative Studies of HERC Economists

Study	CSPCC	Economist
CSP 424: Clinical Outcomes, Revascularization and Aggressive Drug Evaluation (COURAGE)	West Haven	Paul Barnett
CSP 474: Radial Artery vs. Saphenous Vein Grafts in Coronary Artery Bypass Surgery	Palo Alto	Todd Wagner
CSP 481: The Home International Normalized Ratio (INR) Monitor Study (THINRS)	Palo Alto	Ciaran Phibbs
CSP 512: OPTIMA – A Tri-National Randomized Controlled Trial to Determine the Optimal Management of Patients with HIV Infection For Whom First and Second-Line Active Anti-Retroviral Therapy has Failed	West Haven	Wei Yu
CSP 519: Integrating Clinical Practice Guidelines for Smoking Cessation into Mental Health Care for Veterans with Post Traumatic Stress Disorder	Palo Alto	Mark Smith
CSP 530: Intensive vs. Conventional Renal Support in Acute Renal Failure	West Haven	Mark Smith
CSP 553: Adjuvant Therapy in Patients with Locally Advanced, Node-negative Prostate Cancer, Treated with Prostatectomy	Palo Alto	Wei Yu

5. Recent Significant Economic Findings of CSP Studies Involving HERC Economists

In the past year, HERC economists conducted continuing analyses on three studies. A fourth study entered the primary analysis phase. Results from the economic components of these studies yielded the following notable findings:

- Geriatric Evaluation and Management (GEM) units were not less expensive than usual care. However, GEM patients had significantly fewer nursing home admissions The paper reporting these results was published in Medical Care (CSP 006).

- Relatively small differences in PTSD symptom levels were associated with notable differences in labor market outcomes. This implies that even partial improvements in PTSD symptom levels may help patients achieve more employment and more income (CSP 420). This finding was published in Mental Health Services Research.

- Positron emission tomography (PET) was found to be a cost-effective in the diagnosis of solitary pulmonary nodules if it is used selectively, when pre-test probability of lung cancer and computed tomography findings disagree, or in patients with intermediate pre-test probability who are at high risk for surgical complications. This finding was published in the Annals of Internal Medicine. Meta-analyses of PET test characteristics were published in JAMA and the Annals of Internal Medicine. The results of a survey of study sites on the cost of PET were published in the

American Journal of Roentgenology. CSP approved a supplemental study to combine study results with administrative data. Two papers have been drafted. The first describes the pretest characteristics that are associated with the highest cancer risk, critical information to identify individuals who can benefit the most from a PET scan. This paper has been revised an resubmitted to Chest. The second paper examines the relationship of treatment, cost, and survival of individuals who participated in CSP 27 to their test results and malignancy status. This follow-up of CSP 27 participants will help identify how clinicians acted upon test results, and the resulting outcomes.

6. Leadership in CSP

HERC convenes quarterly conference calls of CSP economists. HERC economists are joined by economists affiliated with the Hines and Perry Point Coordinating Centers and other VA economists who work on CSP studies. Participants share information on economic data and methods. For example, a recent topic has been the methods of determining the cost of non-VA health care received by study participants. The calls also provide a forum for economists to reach consensus, so that CSP has a consistent approach to economic evaluation. These calls are a way for HERC to identify issues of importance to CSP, and to provide help to other CSP economists. HERC economist Mark Smith chairs these meetings.

HERC health economist Paul Barnett chaired a committee to evaluate how CSP can conduct good clinical practice monitoring with electronic databases. This committee researched available data and software and developed a white paper with four recommendations for action.

Barnett also participated in the committee that drafted performance criteria for CSP centers.

7. Consulting Service for Other Cooperative Studies Program Economists

HERC assists other economists who work with CSP. Below is a list of CSP projects for which HERC provided assistance.

- CSP 385, Urgent Revascularization in Unstable Angina (AWESOME). The Hines CSPCC conducted a retrospective analysis of this trial comparing angioplasty to bypass surgery in unstable angina patients. HERC helped Hines CSPCC economist Kevin Stroupe develop cost determination methods, providing him with information on the average cost of the types of VA care received by patients, assistance in development of a cost model for inpatient cardiology care, and evaluation of statistical significance using bootstrapping. A HERC economist is a co-author on the final study manuscript which is in press in Circulation.

- CSP 430, Reducing The Efficacy-Effectiveness Gap In Bipolar Disorder. HERC provided methods advice on how to obtain the costs of different inputs (e.g. labor, drugs, etc.).

- CSP 498, The Veterans Affairs Open Versus Endovascular Repair (OVER) Trial for Abdominal Aortic Aneurysms. HERC helped Yvonne Jonk determine how to measure costs of care for this study. HERC has also provided periodic consulting to Dr. Jonk on methodology issues.

- CSP 504, Risperidone Treatment for Refractory Post Traumatic Stress Disorder. This trial is investigating whether the second-generation antipsychotic risperidone can improve PTSD symptoms for patients with refractory illness. HERC provided information to Perry Point CSP economist Douglas Bradham on non-VA care recorded in VA utilization databases.

- CSP 535, Anabolic Steroid Therapy on Pressure Ulcer Healing in Persons with Spinal Cord Injury. This trial is looking at the effect of anabolic steroids on difficult-to-heal pressure ulcers in spinal cord injury patients. HERC reviewed the economic parts of the protocol and provided

feedback to Perry Point economist Douglas Bradham. This resulted in major revisions to the economic analysis section of the proposal.

- CSP 550, Outcomes and an Economic Analysis of Store and Forward Teledermatology. This study, which was approved but not funded, would have evaluated a teledermatology technology. During the planning process, HERC staff consulted with Durham economist Santanu Datta about tracking dermatology care in DSS datasets.

- CSP 556, The Effectiveness of rTMS in Depressed VA Patients. If approved, this trial will investigate the effectiveness of a novel treatment method for depression. During the planning process, HERC consulted with Perry Point economist Douglas Bradham about grouping outpatient stop codes into broad categories of care (e.g., medical/surgical, nursing, psychiatry, etc.) HERC has also provided periodic consulting to Dr. Bradham on methodology issues.

- CSP 557, VA Coronary Artery Re-Vascularization in Diabetes Study- (VA CARDS). HERC consulted with the study proponent when he was preparing the letter of intent about the design of the economic analysis.

- CSP 561, Evaluation of an Electronic Chart Reminder for Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. HERC has provided periodic consulting to Dr. Bradham on methodology issues.

8. CSP Guidelines for Utility Assessment

HERC is completing a guide to utility assessment, designed for an audience of CSP economists, biostatisticians, and planning committees. Utilities are assessed to represent patient health status as quality adjusted life years (QALYs), the measure used in cost-effectiveness analysis. Several different methods have been used in CSP trials. Since the method can affect the study results, this is a very important issue for CSP economic analyses. The draft manuscript, developed by HERC research psychologist Forest J. Baker, described seven methods of assessing utilities and criteria for assessing the merits of each method. It is now under internal review and will include an up-to-date summary of CSP experience in measuring utilities. Seminars describing this overview were presented to VA health economists in 2005 and 2006 and are now available on the world wide web (hsrd.webex.com).

Baker also reviewed the literature on quality of life assessments in HIV/AIDS, evaluating instrument responsiveness to symptoms and disease status, and instrument validity by assessing correlations among the different instruments and subscales of the SF-36 and the HIV-MOS. This manuscript is now under review.

This project also resulted in recommendations about the most appropriate way to measure HRQL utilities in patients with arthritis, to plan CSP 551.

B. Development of the VA Health Economics Infrastructure

1. Development of Comprehensive VA Cost Estimates

One of the major obstacles to conducting cost-effectiveness in VA Cooperative Studies has been the difficulty in estimating VA costs. HERC estimates the costs of every VA inpatient stay and outpatient visit, centralizing a task that was formerly performed by each economist assigned to a Cooperative Study.

These cost databases are used on CSP trials and have greatly increased the efficiency and quality of economic analyses. HERC guidebooks describe how the inpatient and outpatient cost estimates were derived and how to use them.[2;3] These standardized estimates can be used for all encounters where the

trial doesn't directly affect the care provided. In most trials, the HERC average cost estimates can be used for all follow-up care. Methods to prepare these estimates were peer-reviewed and were among the seven papers authored by HERC staff that were published in a special issue of Medical Care Research and Review.

HERC has used the Cost Distribution Report (CDR) to estimate costs. The CDR has been replaced by the DSS Monthly Product Cost Report (MPCR). HERC analyzed the MPCR and determined that it does not distribute all economic costs to patient care departments. It thus will not be useful for producing the HERC cost estimates. After careful examination, HERC determined that the best alternative was to build a department-level cost database by aggregating cost estimates in the DSS inpatient and outpatient National Data Extracts (NDEs).

From its work creating outpatient cost estimates, HERC identified an important limitation of VA administrative data. The creators of the VA outpatient file imposed a rule that eliminated repeated use of a procedure (CPT) code within an encounter. However, many codes are designed to be repeated, for example, to represent each 15 minutes of service. The outpatient database was also limited to a maximum of 15 codes per encounter. A HERC technical report found these design limitations excluded 12% of VA outpatient workload.[4] As a result of this work, VHA National Data Systems has modified VA outpatient data to allow 20 codes per encounter, and to permit repeat use of a code within an encounter. VHA used the modified design to create a revised FY 2004 database, and is applying it to the 2005 data.

HERC completed inpatient cost estimates through FY2005. The modification to the VA outpatient database requires that HERC modify its methods. FY2005 outpatient cost estimates will not be released until the summer of 2006.

HERC created a database with the annual cost incurred by each VA patient. HERC annual cost totals were combined with patient-level pharmacy costs from DSS. HERC created annual patient-level cost databases for each fiscal year from 1998 through 2004. The 2005 cost database will be available in the summer of 2006. It is documented in a technical report.[5]

2. Evaluation and Documentation of DSS Cost Data

VA adopted the Decision Support System (DSS) to estimate the cost of health care products and patient encounters. HERC has devoted a great deal of effort in evaluating and documenting DSS in the belief that it will eventually become the primary source of VA cost data. DSS is already a valuable source of information for economic analyses of CSP trials. It includes data on some types of care not captured in the NPCD and PTF files, most notably outpatient pharmacy costs.

HERC produced a guidebook on the VA Decision Support System (DSS) national data extracts.[6] A major revision and update of the DSS guidebook was released in the summer of 2005.

HERC evaluated the use of DSS cost estimates for cost-effectiveness research. HERC economists Wei Yu and Paul Barnett evaluated DSS national extracts and found some discrepancies between DSS and other administrative data.[7,8,9] This comparison is now being updated. DSS data were used as an alternate method of estimating VA costs in an economic evaluation of data from the VANQWISH trial.[10] Results were qualitatively the same regardless of whether HERC or DSS data were used. We are now evaluating the use of DSS in other CSP trials.

HERC also compared DSS cost estimates to HERC average cost data. Although the overall correlation between the sources is high, there are differences. HERC technical reports of these comparisons are available for inpatient care and the person-level data.[11,12] A report comparing HERC and DSS outpatient cost estimates is nearly complete. HERC is focusing its efforts on helping researchers identify DSS estimates that appear problematic.

HERC is also documenting DSS department-level cost data. HERC is evaluating other new DSS files and exploring their usefulness for CSP trials. These include data on all laboratory and imaging tests, the

results of selected laboratory tests, and dispensed prescriptions. The laboratory and pharmacy data are being used to provide comparisons for study and non-study patients for the THINRS trial (CSP 481). HERC collaborates with the VA Information Resource Center (VIReC), the Bedford Technical Support Office (BTSO), and the VISN Service Support Center (VSSC) to provide information and training to research users of DSS.

3. Improvement of Other Methods for Determining VA Health Care Costs

In addition to average cost and DSS data described above, HERC developed other methods of measuring the costs of VA health care and guidelines on when it is appropriate to use each method.[13]

The most important of these is micro-costing. This method is often needed to estimate the cost of innovative interventions that are being evaluated in a Cooperative Study. Average cost methods, which rely on administrative data and some strong assumptions, are often inadequate for this task; DSS data are also unlikely to accurately represent the cost of this care. HERC has produced a guidebook on use of micro-costing methods in VA.[14]

HERC issued a new technical report documenting methods of estimating the wages of types of VHA employees.[15] A second technical report evaluated information on dialysis use and costs in the VA databases.[16] A third technical report describes the Fee Basis data, a source of information on non-VA care paid by VA.[17] HERC created a bibliography that list more than 150 VA cost studies published over the last 25 years. It is updated periodically and available for download from the HERC web site. The special issue in Medical Care Research and Review included HERC papers on VA pharmacy costs, micro-costing, and a comparison of costing methods.

HERC has also developed guidance for VA researchers on instruments for capturing patient reported health care costs such as use of non-VA care and travel costs.

HERC economist Todd Wagner co-authored a meta-analysis on the accuracy of self-reported health care utilization[1819]. This is important for CSP because many trials estimate non-VA costs using self-reported utilization.

4. HERC Training Activities

The HERC training program consists of two major activities: an economics course and a monthly seminar.

The HERC course in health economics is an introduction to cost-effectiveness analysis with emphasis on methods of VA cost determination. It consists of 15 hours of lecture intended to help economists who are new to the VA become established as VA investigators. Students also include VA clinicians and managerial staff new to research. The course is now being taught for the fourth time. Classes are held twice a month using a distance learning technology, a web broadcast and simultaneous telephone conference call. Findings from the preference assessment project have been incorporated into the course. Other topics include VA cost data, determination of VA health care cost by micro-costing and average costing methods, DSS, Medicare databases, cost-effectiveness research, and medical decision-making models.

The Seattle ERIC hosts an annual summer session that features courses in epidemiology, biostatistics, and research methods. HERC economists presented a seminar on economic methods at the 2005 and 2006 sessions.

HERC also hosts a monthly seminar where VA economists present their research results to their peers. Seminars include presentations of studies involving cost determination, cost-effectiveness analysis, and other health economics studies. The teleconferences also provide economists with continuing education on newly evolving data sources, such as the new DSS national extracts. These seminars use WebEx technology that combine graphical and audio presentations and allows real-time interaction with students.

HERC has provided an instructor for the CSP randomized clinical trials course. HERC also continues to offer workshops at VA research meetings. Past workshops have focused on cost determination issues, including use of DSS national data extracts, the HERC average cost datasets, and micro-cost methods.

5. Other Activities in Support of VA Cost-Effectiveness and Health Economics Research

HERC conducts a number of other activities that support cost-effectiveness and health economics research within VA. HERC economists helped draft the HSR&D *Information for Applicants and Reviewers on Cost Analyses* in 1997 and updated these guidelines in 2001 and 2004.

HERC health economists help CSP investigators, biostatisticians, and economists from other coordinating centers, as well as researchers and managers from throughout VA. The consultations have been given via e-mail, telephone, and in person. A weekly call schedule has been implemented so that a Ph.D. economist is always on duty to answer requests. HERC handled 149 help requests in the last 12 months and a total of 964 requests since the help desk was opened in November 1999**.** HERC measures customer satisfaction with a follow-up survey and provides follow-up customer service support.

To make its research on costing methods more accessible, HERC published a supplement to the September 2003 issue of Medical Care Research and Review. Entitled "Estimating VA Treatment Costs: Methods and Applications," it featured six articles describing HERC efforts to measure VA costs and one that applied these methods to estimate the costs of chronic conditions among VA users. The issue also featured two commentaries from non-VA experts.

HERC offers a variety of resources on its web site: www.herc.research.med.va.gov. The site features essays with details of the three cost methods: average costing, micro-costing, and the Decision Support System. Also available in PDF format are copies of articles in the September 2003 supplement to Medical Care Research and Review as well as articles in a 1999 VA supplement to Medical Care. Additional web resources include a searchable database of health economics experts, an e-mail link to submit help requests, answers to 59 Frequently Asked Questions, links to HERC's technical papers and other publications, and training materials for the Health Economics Seminar Series course. A major change in the organization of the HERC website was completed in 2006.

C. Service Provided to the VA Research Service

1. Study of the economic impacts of VA research

In response to a request from CRDO received in 2006, HERC evaluated potential methods of estimating the economic impact of VA research. HERC economists identified individuals to participate in a project steering committee, and participated in conference calls to discuss potential methods. As a result of these discussions, HERC is now developing information on the economic impacts of VA research for potential use in budget submissions from VA research service.

2. Assistance to Deputy CRDO

Mark Smith was detailed to ORD part-time in April and May 2006. He assisted the Deputy CRADO in several ways: developing Office of Management and Budget (OMB) performance standards for ORD; planning the economic analysis of a clinical trial concerning compensation and pension exams; and developing a plan to estimate the impact of the ORD research program on VA physician recruitment and retention.

3. Determining the Cost of Institutional Review Boards

Many claim that Institutional Review Boards (IRBs) are under-funded and/or under-staffed, compromising IRB quality and the protection of human subjects from research risks. Little is known, however, about the actual costs of operating an IRB. In response to a request from the VA Chief Research and Development Officer, the cost of operating a human subjects' protection program was estimated. Todd Wagner led the

project. Results were published in a HERC technical report.[20] Dr. Wagner and colleagues from University of Rochester and University of North Carolina expanded this research, publishing it in Academic Medicine in 2003.[21] A second, more detailed study on the costs of IRBs was conducted. In addition to confirming the initial study's results, large economies of scale were found; large review boards handled 50 times the workload of small boards at only four times the cost. A paper describing these results was published in Medical Care.[22] A proposal for further research on this topic is under review at NIH.

4. Developing a New Financing System for VA Research Administration

The VA Office of Research and Development (ORD) asked HERC to develop a new method for allocating research administration funds, also known as 101 funds. Dr. Wagner and colleagues conducted in-depth interviews with staff from eight VA health care systems representing different facility sizes and geographic areas. They then surveyed all Administrative Officers (AOs) in the research offices, asking about staff, expenditures, and revenues. They used the results to investigate the underlying needs of research administration at VA health care systems. Through an iterative process, they developed three alternative allocation models to meet these needs. They then compared the models through a simulation exercise. A final report was submitted October 2002.

5. Biostatistical Reviews for VA Medical Research Service

HERC health economists assist CSP with biostatistical review on merit review applications for funding from the VA Clinical and Laboratory Research Services. The economists typically review 1-3 proposals each year on an as-needed basis.

6. Service on VA Advisory and Steering Committees

HERC health economists serve on the following VA national advisory committees and steering committees:

- QUERI Research and Methodology Committee. The Quality Enhancement Research Initiative (QUERI) is a national program that funds efforts to improve the quality of VA health care. Mark Smith participates in the Research and Methodology committee. This committee provides primary oversight of program, reviewing the strategic plan and progress of the 10 QUERI disease-specific coordinating centers. Smith attends committee meetings and provides reviews of the economic components of QUERI centers' research programs. Since Smith is also the director of the HERC project to assist economists who evaluate QUERI programs (see below), he is a non-voting member of the R&M committee, to avoid any conflict between these roles.

- QUERI Substance Use Disorders Steering Committee. Paul Barnett serves on the executive committee Substance Use Disorders QUERI.

- VA Information Resource Center (VIREC) Technical Advisory Committee. VIREC is an HSR&D center that supports the data information needs of VA researchers. Wei Yu serves on the center's Technical Advisory Committee. He also serves on VIREC's Medicare Data Request and Review Board, along with Ciaran Phibbs. Furthermore, Wei Yu is a member of VIREC's Long-Term Care Data Task Force.

- VA Task Force for Dementia Data Registry. This task force was created by Central Office to provide advice on the methods and structure for a national VA registry of patients with dementia. Wei Yu is a member of this task force.

- VA Health Services Research and Development Ethics Committee. This national VA committee was established to provide advice on how to improve the research review process. Todd Wagner serves on this committee.

- Measurement Excellence Training Resource and Information Center (METRIC). METRIC is an HSR&D national resource center that provides guidance and training on psychometrics and the choice of survey instruments. Mark Smith serves on the METRIC Steering Committee.

- Mental Health QUERI ReTIDES Project. ReTIDES is a Mental Health QUERI project testing a large-scale implementation of collaborative treatment for depression. Mark Smith chairs the ReTIDES Steering Committee.

- VA CSP #535 Data Safety and Monitoring Board. The study of anabolic steroid therapy on pressure ulcer healing in person with spinal cord injury is a VA CSP study coordinated by VA CSP statistical coordinating center at Perry Point, NJ. Wei Yu serves as a member of the DSMB for this study.

- VA Center for Patient Healthcare Behavior, Nashville. The Center for Patient Healthcare Behavior is a newly funded center at VA Tennessee Valley Health Services Research Center under the VA HSR&D TREAP program. Wei Yu serves as a member of the steering committee.

7. Service on VA Scientific Review Panels

HERC economists serve on the Scientific Merit Review Board (SMRB, formerly SREB) of the VA HSR&D Service. Wei Yu served from 1999 until March 2005. Mark Smith served as an *ad hoc* SMRB reviewer in January 2004 and in August-September 2005. Ciaran Phibbs was an ad hoc SMRB reviewer in September 2004 and Todd Wagner served in this capacity in March 2005. Patsi Sinnott is serving on this panel in 2006.

Mark Smith serves as a reviewer for QUERI Service Directed Project and Rapid Response Project proposals.

8. Service to the VA Quality Enhancement Research Initiative (QUERI)

HERC is undertaking a new project to support economic evaluations of programs to improve health care quality being conducted by the VA Quality Enhancement Research Initiative (QUERI). HERC staff advises QUERI leaders on economic research plans. They will survey QUERI researchers about training needs will provide technical support for economic projects. Mark Smith leads these efforts.

As noted above, Mark Smith participates in the QUERI Research and Methodology committee and Paul Barnett serves on the Steering Committee of the Substance Use Disorders QUERI.

Mark Smith provided additional support to the QUERI program during a detail to ORD in April-May 2006. His work included developing a new Rapid Response Project (RRP) solicitation and serving as a reviewer of Service Directed Project (SDP) and RRP concept papers and proposals.

D. Projects in Service to VA Management

1. Assessing VA Physician Productivity

The VA National Leadership Board authorized a subcommittee to consider methods for documenting physician productivity. The subcommittee identified two primary methods: hiring contract coders or having physicians code their procedures. It was felt that a demonstration project should be considered. The subcommittee contacted HERC, and Todd Wagner and Ciaran Phibbs assisted the subcommittee in putting together a proposal. The proposal was sent to the NLB, where it was deferred due to the cost of the demonstration project.

2. Other Assistance to VA Central Office

HERC has provided other assistance to VA Central Office, including the following activities:

- At the request of the Director of the Women's Veterans Health Program, Ciaran Phibbs reviewed an analysis by an outside consultant to estimate the potential cost to VA of expanding coverage to include care for the infant when VA covers the pregnancy and delivery. He concluded that this analysis was flawed and conducted a new analysis using data from his NIH funded project on neonatal care. Dr. Phibbs found that the expected cost to VA would be only about 40% of what was originally estimated by the outside consultant. These data are being included in the information VA submits to Congress in support of legislation to expand VA benefits.

- Mark Smith assisted Neil Thakur, head of the management consultation service in VACO, by developing a proposal to study the relation between PTSD benefits and return-to-work behavior among Vietnam-era veterans.

- Ciaran Phibbs helped VISN Service Support Center staff develop methods to estimate the potential non-VA costs of services currently provided by VA to support management make-or-buy decisions.

- VA Central Office asked HSR&D to review a study on the additional cost of adopting optimal, evidence-based care for serious mental illness, substance use disorders, and PTSD. Paul Barnett served on the HSR&D panel that reviewed this study.

- HERC provided the Mental Health Strategic Health Services Group with data on recent trends on VA expenditures for specialized treatment for addictive disorders.

- The VA HS&RD management consultation service requested an estimate of the possible cost savings from adoption of lower cost anti-hypertensives. Paul Barnett responded to this request.

- Paul Barnett briefed CRADO on comparisons of VA to Medicare costs and evaluations veteran's dual use of Medicare and VA.

3. Assistance to the Sierra-Pacific VISN

VA's method of allocating its health care resources, the Veterans Equitable Resource Allocation (VERA) system, uses capitation payments to set regional budgets. It shifts control over facility budgets to the 22 regional networks. HERC provides technical assistance to the staff of the Sierra Pacific Network to develop a method to allocate funds to VA facilities in Northern California, Nevada, and Hawaii. Paul Barnett has participated in the extensive deliberations by the network's fiscal management group and executive leadership committee and helped design an allocation method to reflect the new incentives under VERA. As a result of these meetings, facility budgets are determined by the number of VA health care users living in the geographic area served by each facility, adjusted to reflect patient referrals. HERC staff continues to do analysis in support of this budget process.

4. Nursing Wages

Ciaran Phibbs evaluated the 1990 VA Nurse Pay Act, which changed the way VA set RN salaries from a national wage scale to setting salaries in each local market to match prevailing wages. His research found that this policy increased recruitment and retention of VA nurses.[23],[24] It also found that in small markets, where VA was a major buyer of RN services, non-VA hospitals responded to VA wage increases. The results of this research were reported by VA to Congress to help consider the future of this policy. The manuscript with the results from this study is under review.

5. Effect of Information Technology on Patient Outcomes and Nurse Staffing

Ciaran Phibbs is collaborating with UCSF in a study to evaluate the affects of the VA implementation of an electronic medical record (EMR) and a bar coding medication administration (BCMA) system on preventable adverse events for inpatients and on how these systems affect nurse staffing. While the potential for both of these technologies to prevent adverse patient events is well recognized, there is no large-scale study of their effects. This study will exploit that the VA is a large, relatively homogeneous system, and that both of these technologies were implemented at varying times in different medical centers, to statistically identify the relationship between each technology and potentially preventable adverse inpatient events. Further, this study will look at how these technologies affect nurse staffing. The common belief is that these technologies will be labor saving, but there are some indications that they don't reduce labor costs, and some indications that they could increase labor requirements. This study will be the first study to systematically examine how EMRs and BCMAs affect nurse staffing.

E. Service Provided to the Medical Research Community

HERC health economists have served as reviewers for the following journals since 1999: BMJ, JAMA, Medical Care, Health Services Research, Addiction, Addictive Behaviors, American Journal of Health Promotion, American Journal of Managed Care, American Journal of Obstetrics and Gynecology, American Journal of Preventive Medicine, American Journal of Public Health, Drug and Alcohol Dependence, Effective Clinical Practice, Health Affairs, Industrial Relations, Inquiry, Intensive Care Medicine, International Journal of the Economics of Business, Journal of the American Geriatrics Society, Journal of Clinical Epidemiology, Journal of Health Economics, Journal of Human Resources, Journal of Information Technology in Healthcare, Journal of Rural Health, Journal of Studies on Alcohol, Journal of Women's Health, Pharmacoeconomics, Policy Studies Journal, Preventive Medicine, Social Science and Medicine, and Southern Economic Journal.

Ciaran Phibbs serves as one of the three leaders of the expert panel for the Leapfrog Group's Evidence Based Hospital Referral program. Dr. Phibbs serves on the steering committee of the Health Services and Policy Research scholarly concentration at the Stanford University School of Medicine. He was an invited speaker at the NICHD Conference, "Research on Prevention of Bilirubin-Induced Brain Injury and Kernicterus: Bench-to-Bedside." Dr. Phibbs also served on the Clinical Advisory Panel of a project by the Blue Shield Foundation of California to define the essential benefits for a universal health insurance plan in 2003. Dr. Phibbs served on the Agency for Healthcare Quality and Research's Health Care Research Training study section from 1999-2001, and chaired Special Emphasis Panels for this study section in 2002 and 2005. He has served as an ad hoc reviewer for NICHD, the Wellcome Trust, the Alberta Heritage Foundation for Medical Research, the Anemia Institute for Research and Education, the Canadian Institutes of Health Research, and the Robert Wood Johnson Foundation.

Todd Wagner reviewed grants for the NIH National Human Genome Research Institute, National Institute on Aging, National Institute of Mental Health, National Institute of Diabetes and Digestive and Kidney Diseases, the CDC, Alberta Heritage Foundation for Medical Research, and Mexico's Public Health Service (Instituto Nacional de Salud Publica). He was a member of the Health Information Technology Leadership Panel, which was formed by the director of the Office of the National Coordinator for Health Information Technology, in the Department of Health and Human Services. He is the Co-Chair of the Committee on Economics of the International Consultation on Incontinence.

Mark Smith was on the abstract review committee of the 2003 AcademyHealth Annual Research meeting. He represented HERC at an AHRQ meeting in May 2006, entitled "Integrating Cost-Effectiveness Analysis Considerations into Health Policy."

Wei Yu was the Chair (1998-2005) and member (2006-present) of the Finance Committee of the Chinese Economist Society. He is also program associate director for the Stanford University China-US postdoctoral training and research program on aging studies (10/2001 - present) that is funded by the NIH Fogarty International Center.

Patricia Sinnott is a lecturer in the Doctoral Program in Physical Therapy at UCSF/SFSU, teaching the course sections in health policy and co-teaching a course in evidence-based medicine. Dr. Sinnott is an expert for the California Health Benefits Review, and further serves on the Health Policy Task Force for the American Physical Therapy Association.

F. Faculty Appointments

Paul G. Barnett, Ph.D.

Consulting Associate Professor
Department of Health Research and Policy
Stanford University School of Medicine

Associate
Center for Primary Care and Outcomes Research
Stanford University School of Medicine

Staff Research Associate
Treatment Research Center, Department of Psychiatry
University of California, San Francisco

Ciaran S. Phibbs, Ph.D.

Consulting Associate Professor
Department of Health Research and Policy and Department of Pediatrics
Stanford University School of Medicine

Associate
Center for Primary Care and Outcomes Research
Stanford University School of Medicine

Mark W. Smith, Ph.D.

Associate
Center for Primary Care and Outcomes Research
Stanford University School of Medicine

Todd H. Wagner, Ph.D.

Consulting Assistant Professor
Department of Health Research and Policy
Stanford University School of Medicine

Fellow
Center for Primary Care and Outcomes Research
Stanford University School of Medicine

Scientist
Psychiatry and Behavioral Sciences

Wei Yu, Ph.D.

Fellow
Center for Primary Care and Outcomes Research
Stanford University School of Medicine

Patricia Sinnott, Ph.D.

Lecturer
Graduate Programs in Physical Therapy
University of San Francisco
San Francisco State University

Associate
Center for Health Policy/Center for Primary Care and Outcomes Research
Stanford University School of Medicine

G. HERC Staff by CSP Project

Study Number	Economist	Research Health Science Specialist(s)	Coordinating Center
Studies Being Planned			
562	Ciaran Phibbs		Boston
565	Patsi Sinnott		West Haven
568	Paul Barnett		Palo Alto
Approved Studies - -Awaiting Start-up			
558	Todd Wagner		West Haven
Funded Studies – In Start-up			
551	Ciaran Phibbs		Boston
555	Doug Leslie, Paul Barnett		Boston
560	Todd Wagner	Andrew Siroka	Boston
Ongoing Studies – Patient Accrual			
474	Todd Wagner	Leonor Ayyangar	Palo Alto
519	Mark Smith	Shuo Chen, Andrew Siroka	Palo Alto
530	Mark Smith	Sam Richardson, Andrew Siroka	West Haven
553	Wei Yu	Andrea Shane	Palo Alto
146	Paul Barnett Wei Yu Patsi Sinnott	Vilija Joyce	Palo Alto
Ongoing Studies – Patient Follow-up			
424	Paul Barnett	Shuo Chen	West Haven
481	Ciaran Phibbs	Pon Su	Palo Alto
512	Wei Yu	Vandana Sundaram, Vilija Joyce, Adam Chow	West Haven
Primary Analysis and Manuscript Writing			
027	Paul Barnett	Lakshmi Ananth, JoKay Chan	Palo Alto
Continuing Activity			
006	Ciaran Phibbs		Palo Alto
385	Kevin Stroupe, Paul Barnett		Hines
Completed Projects			
020	Ciaran Phibbs		Palo Alto
368A	Paul Barnett		Palo Alto
420	Mark Smith		Palo Alto
1008	Paul Barnett		Palo Alto

H. HERC Publications and Presentations 2002-2005, Tally by CSP Study

CSP No.	Title	Peer Reviewed Journal Publications	Abstracts/ Presentations	Other	Total
006	Effectiveness of Geriatric Evaluation and Management Units (GEM)	2	1		3
027	FDG Positron Emission Tomography (PET) Imaging in the Management of Patients with Solitary Pulmonary Nodules (SNAP)	4		1	5
146	Preference Measurement for Trial-Based Economic Evaluations			1	1
368A	VA Non Q-wave Infarction Strategies in Hospital (VANQWISH)	1			1
385	Urgent Revascularization in Unstable Angina (AWESOME)	1			1
420	Analysis of Health Care and Work among Veterans with PTSD	1			1
424	Clinical Outcomes, Revascularization, and Aggressive Drug Evaluation (COURAGE)	2		1	2
481	The Home International Normalized Ratio (INR) Monitor Study (THINRS)	1			1
512	OPTIMA – A Tri-National Randomized Controlled Trial to Determine the Optimal Management of Patients with HIV Infection For Whom First and Second-Line Active Anti-Retroviral Therapy has Failed		3		3
519	Integrating Clinical Practice Guidelines for Smoking Cessation into Mental Health Care for Veterans with Posttraumatic Stress Disorder			1	
530	Intensive vs. Conventional Renal Support in Acute Renal Failure (ATN)	1		1	2
-	Health Economics Resource Center	53	65	33	151
	Total	**66**	**69**	**38**	**171**

I. Center Publications and Conference Presentations 2002-2006

Peer-Reviewed Journal Publications

Baker L, **Wagner TH**, Singer S, Bundorf MK. Use of the Internet and E-mail for Health Care Information: Results From a National Survey. *JAMA.* May 14 2003;289(18):2400-2406.

Baker LC, **Phibbs CS**, Guarino C, Supina D, Reynolds JL. Within-year variation in hospital utilization and its implications for hospital costs. *Journal of Health Economics.* 2004;23(1):191-211.

Baker LC, **Phibbs CS**. Managed care, technology adoption, and health care: the adoption of neonatal intensive care. *Rand J Econ.* Autumn 2002;33(3):524-548.

Barnett PG. Determination of VA health care costs. *Medical Care Research and Review.* Sep 2003;60(3 Suppl):124S-141S.

Barnett PG, **Chen S**, Boden WE, et al. Cost-effectiveness of a conservative, ischemia-guided management strategy after non-Q-wave myocardial infarction: results of a randomized trial. *Circulation.* Feb 12 2002;105(6):680-684.

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J. HERC Administration

Staff. HERC has six full-time health economists at Menlo Park. The Menlo Park staff also consists of a Project Manager, eight Research Associates providing programming and analytical support, three Research Assistants, and an Administrator. HERC also receives assistance from clinical consultants who provide invaluable assistance on a number of projects, and a decision-modeling expert, Gillian Sanders, PhD.

Health Economics Resource Center Staff
FY2006

Staff	Position
Paul Barnett, PhD	Director & Health Economist
Mark Smith, PhD	Assoc. Dir. & Health Economist
Todd Wagner, PhD	Health Economist
Wei Yu, PhD	Health Economist
Ciaran Phibbs, PhD	Health Economist
Patsi Sinnott, PhD PT MPH	Health Economist
Lakshmi Ananth, MS	Research Associate
Leonor Ayyangar, MS	Research Associate
Shuo Chen, PhD	Research Associate
Adam Chow, BA	Research Associate
Mistry Gage, MPH +	Research Associate
Vilija Joyce, BA	Research Associate
Samuel S. King	Research Associate
Yesenia Luna, MPH *	Research Associate
Sam Richardson, AB *	Research Associate
Pon Su, MS	Research Associate
Sharon Abas, AA	Administrative Officer
Vandana Sundaram, MPH	Project Manager
JoKay Chan, BS	Research Assistant
Andrea Shane, BA	Research Assistant
Andrew Siroka, BA +	Research Assistant
Gillian Sanders, PhD	Medical Decision Analyst
Michael Gould, MD MS	Clinical Expert
Doug Owens, MD MS	Clinical Expert
Mary Goldstein, MD MS	Clinical Expert
Alan Garber, MD PhD	Clinical Expert

+ Hired during FY 2006 * departed during FY2006

Budget. HERC is funded by both the VA Cooperative Studies Program and the VA Health Services Research and Development Service. This support consists of Cooperative Studies core funding, HSR&D support for HERC, and Palo Alto HSR&D Center of Excellence funding. The Cooperative Studies Program provides additional support for the CSP 146 and the ATN, THINRS, SNAP, OPTIMA, and COURAGE studies. HERC also receives funding from HSR&D investigator-initiated projects, an NIH study, a Robert Wood Johnson Foundation grant, QUERI, and a RR&D Service investigator-initiated project. The annual budget for HERC and its investigators for FY2006 was $1,752,038.

Health Economics Resource Center
FY2006 Budget

Funding Source	No. of Projects	Total Budget
CSP Health Economics Coordinating Center	1	$ 214,394
CSP Project Funds	7	$ 690,374
HSR&D Health Economics Resource Center	1	$ 417,481
HSR&D Project Funds	8	$ 274,121
Other VA Funding[1]	2	$ 100,851
Non-VA [2]	3	$ 54,817
Total	**22**	**$ 1,752,038**

[1] Includes support from the Palo Alto HSR&D Center of Excellence and the Program Evaluation and Resource Center

[2] Includes Robert Wood Johnson Foundation and NIH grants

Steering Committee. HERC is governed by a 5-member steering committee made up of researchers, clinicians, managers, and health economists from VA and outside VA. The steering committee meets by telephone conference call every 3 months, and in an annual face-to-face meeting.

Members of the HERC Steering Committee

Rodney Hayward, MD (Steering Committee Chair)	Director, VA HSR&D, Center for Practice Management and Outcomes Research
Ann Sales, PhD, RN	Health Economist, VA HSR&D Northwest Center for Outcomes Research in Older Adults
Elizabeth Yano, PhD	Deputy Director, Center for the Study of Healthcare Provider Behavior
Pamela Duncan, PhD	Director, Rehabilitation Outcomes Research Center
Marty Charns, DBA	Director, Center for Organization, Leadership, and Management Research
Matthew Maciejewski, PhD	Health Economist, Center for Health Services Research in Primary Care

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